

Exhibit 25

Confidential Subject to Protective Order

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

3 IN RE: ACETAMINOPHEN -) MDL No. 3043
4 ASD-ADHD PRODUCTS)
5 LIABILITY LITIGATION) Case No.
6) 1:22-md-03043-DLC
7 THIS DOCUMENT RELATES TO:)
8) JUDGE DENISE
9 All Cases, 1:22-md-03043) COTE

10
11 WEDNESDAY, SEPTEMBER 6, 2023

12 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

13 - - -

14 Videotaped deposition of Jennifer
15 Pinto-Martin, Ph.D., MPH, held at the offices
16 of Barnes & Thornburg, 1717 Arch Street,
17 Suite 4900, Philadelphia, Pennsylvania,
18 commencing at 8:42 a.m. Eastern, on the above
19 date, before Carrie A. Campbell, Registered
20 Diplomate Reporter, Certified Realtime
21 Reporter, Illinois, California & Texas
22 Certified Shorthand Reporter, Missouri,
23 Kansas, Louisiana & New Jersey Certified
24 Court Reporter.

25 - - -

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1 VIDEOGRAPHER: We are now on
 2 the record. My name is Brian McGee.
 3 I'm a videographer for Golkow
 4 Litigation Services.
 5 Today's date is September 6,
 6 2023, and the time is 8:42 a.m.
 7 This video deposition is being
 8 held in Philadelphia, PA, in the
 9 matter of Acetaminophen (Tylenol)
 10 ASD/ADHD Products Liability
 11 Litigation, MDL Number 3043.
 12 The deponent is Jennifer
 13 Pinto-Martin.
 14 Counsels' appearances will be
 15 noted on the stenographic record.
 16 The court reporter is Carrie
 17 Campbell and will now swear in the
 18 witness.
 19
 20 JENNIFER PINTO-MARTIN, Ph.D., MPH,
 21 of lawful age, having been first duly sworn
 22 to tell the truth, the whole truth and
 23 nothing but the truth, deposes and says on
 24 behalf of the Plaintiffs, as follows.
 25 /

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1 DIRECT EXAMINATION
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. Good morning, Dr. Pinto-Martin.
 4 A. Good morning.
 5 Q. My name is J.J. Snidow, and I
 6 think you understand I represent the
 7 plaintiffs in today's case?
 8 A. I do.
 9 (Pinto-Martin Exhibit 600
 10 marked for identification.)
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Okay. I'm going to show you a
 13 document that I've marked as Exhibit 600 of
 14 your deposition. We'll be going in that
 15 order, from 600 on.
 16 Do you recognize this as your
 17 report in this case?
 18 MR. SNIDOW: Do you need those,
 19 Jim? Yeah, you do.
 20 THE WITNESS: It does look to
 21 be my report with the appendices and
 22 the references and my CV, yes.
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Any changes that you need to
 25 make in that report that you've noticed in

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1 preparing?
 2 A. So, yeah. In the last week or
 3 so I just was reading through it and found a
 4 few things that I would like to change.
 5 THE WITNESS: Do I give him
 6 this?
 7 MR. MURDICA: They already have
 8 it.
 9 QUESTIONS BY MR. SNIDOW:
 10 Q. Is it that handwritten note
 11 that you produced?
 12 A. Yes. Yeah. Yeah.
 13 Q. Anything else?
 14 A. No.
 15 Q. So other than those marks that
 16 you made on the handwritten note, everything
 17 else in your report you believe is accurate
 18 as you sit here today?
 19 A. I do.
 20 Q. I'd like you to turn to page 5
 21 of Exhibit 600, which is your report.
 22 A. Uh-huh.
 23 Q. And do you see a paragraph
 24 that's marked 7 there?
 25 A. Yes.

<p style="text-align: right;">Page 18</p> <p>1 Q. Do you see the sentence that 2 begins "because"?</p> <p>3 A. Uh-huh.</p> <p>4 Q. It says, "Because the better 5 designed studies do not report an 6 association, the inconsistency in the studies 7 is an important factor that weighs against a 8 causal conclusion."</p> <p>9 Did I read that correctly?</p> <p>10 A. You did.</p> <p>11 Q. Does that sentence apply both 12 to the ADHD and the ASD literature?</p> <p>13 A. I believe so.</p> <p>14 Q. Okay. And that was important 15 to you as you say here?</p> <p>16 A. Uh-huh.</p> <p>17 Q. So it was important to you that 18 the better-designed studies don't report an 19 association either for ASD or ADHD?</p> <p>20 MR. MURDICA: Objection to 21 form.</p> <p>22 Go ahead.</p> <p>23 THE WITNESS: Correct.</p> <p>24 QUESTIONS BY MR. SNIDOW:</p> <p>25 Q. Correct, all right.</p>	<p style="text-align: right;">Page 20</p> <p>1 at the deposition, period, unless you 2 want to call the Court.</p> <p>3 MR. SNIDOW: Okay. That's 4 fine. I'm going to use this though.</p> <p>5 MR. MURDICA: Okay. Take the 6 marker off. We're not going to mark 7 it, and I'm letting the court reporter 8 know that we won't be marking it as an 9 exhibit.</p> <p>10 If you intend to, let's just 11 call the Court now because it's not 12 happening.</p> <p>13 MR. SNIDOW: Okay.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Dr. Pinto-Martin, do you see 16 this document?</p> <p>17 A. I do.</p> <p>18 Q. All right. Can you tell me 19 what are the better-designed studies for ASD? 20 What are their names?</p> <p>21 MR. MURDICA: J.J., are you 22 going to take that marker off?</p> <p>23 MR. SNIDOW: I'm going to, I 24 promise.</p> <p>25 MR. MURDICA: Okay.</p>
<p style="text-align: right;">Page 19</p> <p>1 All right. Marking another 2 document as Exhibit 601. This is just my 3 handwriting, and I'll give it to you when 4 we're done in a second.</p> <p>5 So tell me what the 6 better-designed studies on ASD are. What are 7 their names?</p> <p>8 MR. MURDICA: J.J., I object to 9 the use of this kind of thing. I 10 don't think you can mark it as an 11 exhibit. We're not going to create 12 plaintiff lawyer-created exhibits 13 here.</p> <p>14 MR. SNIDOW: Jim, objection to 15 form.</p> <p>16 MR. MURDICA: No -- well, hang 17 on. This is different. This is about 18 whether you can create something as an 19 exhibit, and I'm not going to let that 20 happen.</p> <p>21 MR. SNIDOW: Okay. I'll take 22 the marker off if that's what you 23 want.</p> <p>24 MR. MURDICA: You're not going 25 to be able to mark this as an exhibit</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. SNIDOW: Trust me. I 2 promise.</p> <p>3 MR. MURDICA: Okay.</p> <p>4 QUESTIONS BY MR. SNIDOW:</p> <p>5 Q. Dr. Pinto-Martin, what are the 6 names of the better-designed studies for ASD?</p> <p>7 MR. MURDICA: Object to form.</p> <p>8 If you can answer it, go ahead.</p> <p>9 THE WITNESS: So the 10 best-designed study that uses ASD as a 11 diagnostic outcome of the five that I 12 include in my report that look at 13 prenatal acetaminophen exposure and 14 ASD in the child is the Danish 15 National Birth Cohort study, the Liew 16 2016 C study.</p> <p>17 QUESTIONS BY MR. SNIDOW:</p> <p>18 Q. Okay.</p> <p>19 A. And I can go into the 20 reasons --</p> <p>21 Q. Nope. Nope.</p> <p>22 A. -- why I think the others are 23 not as well-designed, if you like, but...</p> <p>24 Q. Yeah.</p> <p>25 Is Liew 2016 the only study</p>

<p style="text-align: right;">Page 22</p> <p>1 that you're referring to in your report when</p> <p>2 you are referring to the better-designed</p> <p>3 studies?</p> <p>4 A. With respect to ASD, yes.</p> <p>5 Q. All right. So just Liew 2016?</p> <p>6 A. Yes.</p> <p>7 Q. For ADHD, when you referred to</p> <p>8 the better-designed studies, which studies</p> <p>9 did you mean?</p> <p>10 MR. MURDICA: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: So the</p> <p>13 best-designed study that looks at</p> <p>14 maternal acetaminophen exposure during</p> <p>15 pregnancy and ADHD as a diagnostic</p> <p>16 outcome is the Gustavson 2021 study,</p> <p>17 which is based on the mother and baby</p> <p>18 cohort from Norway.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Okay. Any other</p> <p>21 better-designed studies that you're referring</p> <p>22 to there for ADHD?</p> <p>23 A. That's the best.</p> <p>24 MR. MURDICA: Objection to</p> <p>25 form.</p>	<p style="text-align: right;">Page 24</p> <p>1 outcomes, so...</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Okay. So let's look at your</p> <p>4 report again. You said, "The better-designed</p> <p>5 studies do not report an association."</p> <p>6 Right?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. I asked you, which</p> <p>11 better-designed studies. You said Liew 2016,</p> <p>12 right?</p> <p>13 MR. MURDICA: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: Uh-huh.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. And my question for you is very</p> <p>18 simple, does Liew 2016 report an association</p> <p>19 between acetaminophen use and ASD?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 QUESTIONS BY MR. SNIDOW:</p> <p>23 Q. Yes or no.</p> <p>24 MR. MURDICA: Asked and</p> <p>25 answered.</p>
<p style="text-align: right;">Page 23</p> <p>1 You can answer.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. So just one for each?</p> <p>4 A. (Witness nods head.)</p> <p>5 Q. So you used the plural there,</p> <p>6 but there's just one for each of them?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: There's one for</p> <p>10 each them.</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Okay. And --</p> <p>13 A. Two studies in total.</p> <p>14 Q. Yeah. And, Dr. Pinto-Martin,</p> <p>15 you mentioned Liew 2016. It's your testimony</p> <p>16 that Liew 2016 does not report an association</p> <p>17 between acetaminophen and ASD?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: Liew 2016 has a</p> <p>21 series of outcome measures that they</p> <p>22 use that include ASD alone, infantile</p> <p>23 autism, ASD with hyperkinetic</p> <p>24 disorder, and the positive association</p> <p>25 was found for a subset of those</p>	<p style="text-align: right;">Page 25</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Does it do that?</p> <p>3 A. It does.</p> <p>4 Q. Okay. So I'm going to cross</p> <p>5 this one off because it does.</p> <p>6 What better-designed --</p> <p>7 A. So --</p> <p>8 MR. MURDICA: Objection to</p> <p>9 form. Hang on. First of all, I have</p> <p>10 to object. I object to form. There's</p> <p>11 no need to raise your voice.</p> <p>12 MR. SNIDOW: Okay.</p> <p>13 MR. MURDICA: Okay? We can</p> <p>14 stay calm and professional all day</p> <p>15 long.</p> <p>16 MR. SNIDOW: Yeah, that's fine.</p> <p>17 MR. MURDICA: Let's try it.</p> <p>18 THE WITNESS: May I --</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Hold on. Hold on. Hold on.</p> <p>21 Let me ask the question.</p> <p>22 The question is, besides</p> <p>23 Liew 2016, are there any better-designed</p> <p>24 studies on ASD that you know of that do not</p> <p>25 report an association between acetaminophen</p>

<p style="text-align: right;">Page 26</p> <p>1 use and ADHD?</p> <p>2 MR. MURDICA: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: The current</p> <p>5 literature does not include any</p> <p>6 better-designed studies.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Okay.</p> <p>9 A. Better-designed is -- we could</p> <p>10 talk about what that means.</p> <p>11 Q. Okay. For Gustavson 2021, is</p> <p>12 it your testimony that Gustavson 2021 does</p> <p>13 not report an association between prenatal</p> <p>14 acetaminophen use and ADHD?</p> <p>15 A. It is.</p> <p>16 Q. Okay. In that entire study?</p> <p>17 MR. MURDICA: Wait. Objection</p> <p>18 to form.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: The authors</p> <p>21 report the previously reported</p> <p>22 association from the same cohort and</p> <p>23 the same set of authors and then apply</p> <p>24 a sibling-control analysis that</p> <p>25 reduces the prior reported association</p>	<p style="text-align: right;">Page 28</p> <p>1 this last time.</p> <p>2 MR. MURDICA: Don't ask the</p> <p>3 same question twice in a row.</p> <p>4 MR. SNIDOW: Okay. Let's go</p> <p>5 off the record.</p> <p>6 VIDEOGRAPHER: The time is</p> <p>7 8:51 a.m. We're off the record.</p> <p>8 (Off the record at 8:51 a.m.)</p> <p>9 VIDEOGRAPHER: The time is</p> <p>10 8:53 a.m., and we're on the record.</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Okay. Dr. Pinto-Martin, do you</p> <p>13 remember the question I asked you?</p> <p>14 A. I don't. I'm sorry.</p> <p>15 Q. Okay. If I look in Gustavson</p> <p>16 2021, am I going to find an association</p> <p>17 between prenatal APAP use and ADHD, yes or</p> <p>18 no?</p> <p>19 MR. MURDICA: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: Gustavson 2021</p> <p>22 will summarize the results from the</p> <p>23 whole cohort, and in that entire</p> <p>24 cohort, as was reported in the prior</p> <p>25 study by Ystrom and Gustavson and</p>
<p style="text-align: right;">Page 27</p> <p>1 to the null.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Okay. But if I just -- if I</p> <p>4 open up Gustavson 2021, and we will, am I</p> <p>5 going to find an association between</p> <p>6 acetaminophen and ADHD in there?</p> <p>7 A. At the end of the day, the</p> <p>8 association that was reported was confounded</p> <p>9 by genetics, and the final outcome there is a</p> <p>10 null finding.</p> <p>11 Q. Okay. Do you remember my</p> <p>12 question, though?</p> <p>13 A. I do.</p> <p>14 Q. Okay. If I open</p> <p>15 Gustavson 2021, am I going to find an</p> <p>16 association between prenatal acetaminophen</p> <p>17 use and ADHD?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 She already answered it.</p> <p>21 THE WITNESS: Go ahead?</p> <p>22 MR. MURDICA: If you want to do</p> <p>23 it again, go ahead.</p> <p>24 MR. SNIDOW: Hey, Jim,</p> <p>25 "objection to form." You know we did</p>	<p style="text-align: right;">Page 29</p> <p>1 others, there was an elevated risk.</p> <p>2 He will then go on to apply a</p> <p>3 sibling-control analysis, which is a</p> <p>4 technique to control for genetic</p> <p>5 confounding, a very important</p> <p>6 confounder in this literature, and</p> <p>7 will report that that prior result is</p> <p>8 reduced to the null.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Okay. So it's a "yes" --</p> <p>11 MR. MURDICA: Object- --</p> <p>12 QUESTIONS BY MR. SNIDOW:</p> <p>13 Q. -- there's going to be an</p> <p>14 association reported in Gustavson 2021?</p> <p>15 MR. MURDICA: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I would say it's</p> <p>18 a yes and a no. It's a yes, and then</p> <p>19 it goes on to refute that finding.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. That's fine. And we'll talk</p> <p>22 about this the sibling control.</p> <p>23 Okay. Dr. Pinto-Martin, this</p> <p>24 is not your first deposition, right?</p> <p>25 A. That's correct.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q. And it looks like you've</p> <p>2 testified on behalf of Pfizer and Ely Lilly</p> <p>3 related to SSRIs?</p> <p>4 A. I've never test -- well, do you</p> <p>5 call a deposition a test --</p> <p>6 Q. I do.</p> <p>7 A. Okay. So, yes, I have.</p> <p>8 Q. Okay. The Nexium litigation,</p> <p>9 gave a dep? It's a PPI.</p> <p>10 A. Yes.</p> <p>11 Q. Okay. I believe you testified</p> <p>12 in a case about twins with autism who were</p> <p>13 exposed to tocolytic agents?</p> <p>14 A. That's correct.</p> <p>15 Q. And then a case where parents</p> <p>16 were occupationally opposed {sic} to a</p> <p>17 pesticide; is that right?</p> <p>18 A. Occupationally exposed, yes.</p> <p>19 Q. Is that it?</p> <p>20 A. In terms of deposition, I</p> <p>21 believe so. I -- you know, it's -- I've been</p> <p>22 doing it for more than ten years, but I</p> <p>23 believe you've captured all the depositions</p> <p>24 I've done, yes.</p> <p>25 Q. How about trial testimony?</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. What cases were those?</p> <p>2 A. I would have to go back and</p> <p>3 look at my records to remember the specifics.</p> <p>4 Q. Okay.</p> <p>5 A. And I believe that they're</p> <p>6 protected, so I don't know that I can</p> <p>7 disclose the specifics of the -- of the</p> <p>8 cases.</p> <p>9 Q. All right. But for testimony,</p> <p>10 depositions or trial, it's been only on</p> <p>11 behalf of defendants?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: For depositions</p> <p>15 and the one time I appeared in court,</p> <p>16 it was -- those were all on behalf of</p> <p>17 defendants, correct.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. And in any of those depositions</p> <p>20 or trial testimony, did you give the opinion</p> <p>21 that the substance caused whatever the injury</p> <p>22 was?</p> <p>23 A. In the depositions and the</p> <p>24 trial testimony that I gave, my opinion was</p> <p>25 that the agent, whatever it was that we were</p>
<p style="text-align: right;">Page 31</p> <p>1 A. I've gone to court once. That</p> <p>2 was in the twin case that you described where</p> <p>3 they were exposed to a tocolytic, which is an</p> <p>4 agent to prevent preterm labor.</p> <p>5 And we went to a court in</p> <p>6 Maryland, and it was in front of a judge, I</p> <p>7 believe it's what's called a Daubert hearing.</p> <p>8 There was not a jury there, but I was</p> <p>9 examined, cross-examined, in front of the</p> <p>10 judge.</p> <p>11 Q. Okay.</p> <p>12 A. That's my only court</p> <p>13 appearance.</p> <p>14 Q. All right. So as far as you</p> <p>15 can remember four -- sorry, five: Four</p> <p>16 depositions and one trial testimony?</p> <p>17 A. That's sounds about right,</p> <p>18 yeah.</p> <p>19 Q. Have you ever testified on</p> <p>20 behalf of a plaintiff?</p> <p>21 A. I've never been deposed. I</p> <p>22 have been engaged on behalf of plaintiffs and</p> <p>23 done consultation, but I've -- that -- those</p> <p>24 consultations have never proceeded to a</p> <p>25 deposition.</p>	<p style="text-align: right;">Page 33</p> <p>1 considering, was not causally related to</p> <p>2 autism spectrum disorder, which was the</p> <p>3 outcome we were looking at.</p> <p>4 Q. In the PPI case, you testified</p> <p>5 that PPIs don't cause fractures?</p> <p>6 A. I don't remember the specifics</p> <p>7 of the PPI case, but I do recall that the --</p> <p>8 that the opinion that I gave was not in --</p> <p>9 did not implicate the agent.</p> <p>10 Q. Do you know whether that label</p> <p>11 now warns about bone fractures?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: I do not.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. Okay. Have you done any</p> <p>17 consulting for pharmaceutical companies?</p> <p>18 A. I have not.</p> <p>19 Q. Do you sit on any boards,</p> <p>20 advisory boards, anything like that, of</p> <p>21 pharmaceutical companies?</p> <p>22 A. I do not.</p> <p>23 Q. Any other work for pharma</p> <p>24 companies I've forgotten?</p> <p>25 A. No.</p>

<p style="text-align: right;">Page 34</p> <p>1 Q. Have they ever sponsored your 2 research?</p> <p>3 A. They have not.</p> <p>4 Q. Have you ever done any media 5 training?</p> <p>6 A. I have not.</p> <p>7 Q. Do you know anyone who works at 8 Johnson & Johnson?</p> <p>9 A. Not to my knowledge.</p> <p>10 Q. Do you know -- before this 11 litigation, did you know any of the other 12 experts involved in this case on either side?</p> <p>13 A. I had certainly heard of some 14 of them. I don't know any of them 15 personally.</p> <p>16 Q. Never met them at academic 17 conferences?</p> <p>18 A. No.</p> <p>19 Q. And that's true both for the 20 defense experts and the plaintiff experts?</p> <p>21 A. Correct.</p> <p>22 Q. So what, that's ten or so?</p> <p>23 A. I think so, yeah.</p> <p>24 Q. And never met any of them in 25 your work as an epidemiologist?</p>	<p style="text-align: right;">Page 36</p> <p>1 policy that all extramural and intramural 2 activities should be cleared through the 3 individual's immediate supervisor when these 4 activities constitute a possible conflict of 5 interest; is that right?</p> <p>6 A. I do sign a conflict of 7 interest statement. I have no conflict of 8 interest, and so there's nothing to report.</p> <p>9 Q. You're an autism researcher 10 professionally, right?</p> <p>11 A. I'm a professor professionally.</p> <p>12 Q. Well, but you focus on autism 13 research?</p> <p>14 A. I do.</p> <p>15 Q. I didn't think you were going 16 to fight me on that.</p> <p>17 And it's your testimony that 18 giving testimony on behalf of J&J about what 19 does and doesn't cause autism doesn't 20 constitute a conflict of interest?</p> <p>21 MR. MURDICA: Objection to 22 form.</p> <p>23 THE WITNESS: I'm not giving 24 testimony on behalf of anyone. I'm 25 giving testimony based on my expert</p>
<p style="text-align: right;">Page 35</p> <p>1 A. No.</p> <p>2 Q. Your billing rate is \$750 per 3 hour?</p> <p>4 A. That's correct.</p> <p>5 Q. And if I'm reading your time 6 entries right, you've spent more than 7 200 hours on this case so far?</p> <p>8 A. That's correct.</p> <p>9 Q. So more than \$150,000 so far?</p> <p>10 A. That's correct.</p> <p>11 Q. Does that money go to you or to 12 Penn?</p> <p>13 A. That money goes to me.</p> <p>14 Q. Do they know you're doing this 15 work?</p> <p>16 A. I do not have to disclose this 17 work by the rules of Penn.</p> <p>18 Q. Sorry. So that's a "no," they 19 do not --</p> <p>20 A. They do not know.</p> <p>21 Q. And you've reviewed the Penn HR 22 policies before deciding not to disclose to 23 them that you're doing this work?</p> <p>24 A. Of course I have.</p> <p>25 Q. And you're aware there's a</p>	<p style="text-align: right;">Page 37</p> <p>1 review of the epidemiologic 2 literature. That's what I was asked 3 to do, and that's what I've done.</p> <p>4 QUESTIONS BY MR. SNIDOW:</p> <p>5 Q. You spent a significant part of 6 your career working to identify modifiable 7 risk factors for ASD; is that right?</p> <p>8 A. I continue to work on that.</p> <p>9 Q. What's a modifiable risk 10 factor?</p> <p>11 A. Modifiable risk factor is 12 something that we -- is a risk factor we can 13 do something about. So it's a risk factor 14 that we can intervene on and thereby reduce 15 the risk of an outcome.</p> <p>16 Q. And I think I know, but just to 17 clarify. When you're using "risk factor," at 18 least in the way you just did, you're 19 referring to something that's actually 20 causal, right?</p> <p>21 A. I'm glad you asked that 22 question.</p> <p>23 Q. Yeah.</p> <p>24 A. And the answer is no. So we 25 have risk factors in epidemiology that get</p>

<p style="text-align: right;">Page 38</p> <p>1 evaluated with respect to their impact on an 2 outcome. So a risk factor can be null; in 3 other words, there is no association. It can 4 be -- it can show evidence of an association, 5 which then puts it in the category of 6 potentially causal, but it's not -- a risk 7 factor does not equate with a causal agent. 8 Q. Well, how about modifiable risk 9 factor? 10 MR. MURDICA: Objection to 11 form. 12 QUESTIONS BY MR. SNIDOW: 13 Q. I mean, if you're going to 14 modify it and expect a lower risk, it seems 15 like it's got to be causal, right? 16 MR. MURDICA: Objection to 17 form. 18 You can answer. 19 THE WITNESS: So there's 20 association and there's causality. 21 And in observational epidemiology, 22 which is what we're talking about 23 here, we are establishing an 24 association. We are looking at the 25 body of evidence to see if the --</p>	<p style="text-align: right;">Page 40</p> <p>1 THE WITNESS: So observational 2 studies are fraught with methodologic 3 challenges, as I'm sure you are aware, 4 and those challenges render any kind 5 of conclusive results about causality 6 challenging. 7 There are instances where a set 8 of observational studies are powerful 9 enough to overcome those challenges, 10 and we are able to say they're -- that 11 the evidence supports a causal 12 association. 13 But that's rare. 14 QUESTIONS BY MR. SNIDOW: 15 Q. Right. 16 Can you give me an example of a 17 modifiable risk factor for anything that's 18 not causal? 19 MR. MURDICA: Objection to 20 form. 21 THE WITNESS: An example of a 22 modifiable risk factor? 23 So -- 24 QUESTIONS BY MR. SNIDOW: 25 Q. Well, let me ask -- let me try</p>
<p style="text-align: right;">Page 39</p> <p>1 there is a credible association 2 between the factor that we're studying 3 and the outcome that we're studying. 4 We cannot establish causality 5 in an observational study because it 6 is not an experiment. 7 QUESTIONS BY MR. SNIDOW: 8 Q. So it's your testimony you 9 can't ever establish causality without doing 10 an RCT? 11 A. That's not what I said. 12 Q. Okay. Well, you said "without 13 doing an experiment." 14 MR. MURDICA: Objection to 15 form. 16 There's no question. 17 QUESTIONS BY MR. SNIDOW: 18 Q. Well, let me ask it again. 19 What did you mean when you said 20 we can't ever establish causality with an 21 observational study because it's not an 22 experiment? 23 MR. MURDICA: Objection to 24 form. 25 Answer it, if you can.</p>	<p style="text-align: right;">Page 41</p> <p>1 some examples first. 2 What's a modifiable risk factor 3 for lung cancer? 4 A. Smoking would be a modifiable 5 risk factor for lung cancer. 6 Q. That one's definitely causal, 7 right? 8 A. I believe that we have strong 9 enough evidence to support there's a causal 10 association between smoking and lung cancer, 11 yes. 12 Q. All right. That's good. 13 Can you think of another 14 modifiable risk factor off the top of your 15 head? 16 A. For lung cancer? 17 Q. Sure. 18 A. So I could imagine that air 19 pollution, you know, you know, cities that 20 have high levels of particulate matter, may 21 have higher rates of lung cancer. 22 The data to determine whether 23 that's causal is going to be very, very 24 challenging because it's an ecological 25 measure. We don't have individual-level</p>

<p style="text-align: right;">Page 42</p> <p>1 exposure, so I would describe that as</p> <p>2 modifiable risk factor for which causal data</p> <p>3 is not established.</p> <p>4 Q. Okay. You're a member of the</p> <p>5 American College of Epidemiology?</p> <p>6 A. Uh-huh.</p> <p>7 Q. That's a pretty well-respected</p> <p>8 organization?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: It is.</p> <p>12 QUESTIONS BY MR. SNIDOW:</p> <p>13 Q. How about the Society For</p> <p>14 Pediatric Epidemiologic Research?</p> <p>15 A. I am a member and -- yes.</p> <p>16 Q. And you used to be president.</p> <p>17 A. I used to be president.</p> <p>18 Q. And that was in '93, '94?</p> <p>19 A. Sounds about right.</p> <p>20 Q. Is that a pretty good</p> <p>21 organization?</p> <p>22 A. I think it's a reputable</p> <p>23 organization, yes.</p> <p>24 Q. Promotes good science, in your</p> <p>25 experience?</p>	<p style="text-align: right;">Page 44</p> <p>1 where that comes from. I don't know</p> <p>2 who says that.</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. Are you a member of the</p> <p>5 National Academy of Medicine?</p> <p>6 A. I am not.</p> <p>7 Q. Are you familiar with the</p> <p>8 International Society of Environmental</p> <p>9 Epidemiology?</p> <p>10 A. I've heard of it.</p> <p>11 Q. A pretty good organization?</p> <p>12 A. I really know nothing about it.</p> <p>13 It's just that I've heard that name.</p> <p>14 Q. How about the Mailman School of</p> <p>15 Public Health?</p> <p>16 A. I certainly know the Mailman</p> <p>17 School of Public Health, yes.</p> <p>18 Q. Is that at Columbia?</p> <p>19 A. It is.</p> <p>20 Q. Outstanding public health</p> <p>21 school?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: It is.</p> <p>25</p>
<p style="text-align: right;">Page 43</p> <p>1 MR. MURDICA: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: In my experience,</p> <p>4 yes.</p> <p>5 QUESTIONS BY MR. SNIDOW:</p> <p>6 Q. Doesn't promote bad science in</p> <p>7 your experience, does it?</p> <p>8 A. That's not been my experience.</p> <p>9 Q. Okay. You're familiar with the</p> <p>10 National Academy of Medicine?</p> <p>11 A. I am.</p> <p>12 Q. Fair to say it's pretty hard to</p> <p>13 get elected to that?</p> <p>14 A. I would agree.</p> <p>15 Q. Extremely impressive</p> <p>16 credential?</p> <p>17 A. It's a hard appointment to get,</p> <p>18 yes.</p> <p>19 Q. It's been described as the</p> <p>20 country's most esteemed and authoritative</p> <p>21 advisor on issues of health and medicine,</p> <p>22 right?</p> <p>23 MR. MURDICA: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: I don't know</p>	<p style="text-align: right;">Page 45</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Do you know anyone there?</p> <p>3 A. I do. I did my postdoc at</p> <p>4 Columbia, so I do know people there.</p> <p>5 Q. Who do you know who?</p> <p>6 A. I know Ezra Susser who was the</p> <p>7 chair of epidemiology for many years. I know</p> <p>8 his father, Mervyn Susser, with whom I</p> <p>9 worked, and his mother is Zena Stein, with</p> <p>10 whom I worked.</p> <p>11 I did my postdoc with a</p> <p>12 physician named Nigel Paneth, who is no</p> <p>13 longer there. Various other folks. I was</p> <p>14 there for four or five years, so...</p> <p>15 Q. And Irwin {sic} Susser,</p> <p>16 outstanding epidemiologist?</p> <p>17 A. So Mervyn Susser is no longer</p> <p>18 alive. That's the father.</p> <p>19 Q. But he was.</p> <p>20 A. He was -- he was a very, very</p> <p>21 good epidemiologist, yes.</p> <p>22 Q. And he was chair of the</p> <p>23 epidemiology department at Columbia?</p> <p>24 A. No, I'm sorry. I think you're</p> <p>25 getting them confused.</p>

<p style="text-align: right;">Page 46</p> <p>1 So Ezra Susser was his son, and</p> <p>2 Ezra was the chair.</p> <p>3 Q. And was he a pretty good</p> <p>4 epidemiologist?</p> <p>5 MR. MURDICA: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: Ezra has a very</p> <p>8 good reputation.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Okay. How big does a risk</p> <p>11 ratio need to be before you would say it was</p> <p>12 strong?</p> <p>13 MR. MURDICA: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: So that's a</p> <p>16 difficult question to answer simply</p> <p>17 because it so depends on the exposure</p> <p>18 that you're looking at, the outcome</p> <p>19 that you're looking at, the quality of</p> <p>20 the data that underlies that exposure,</p> <p>21 but what we do know is that the</p> <p>22 stronger a measure of association is</p> <p>23 the less likely it is to be due purely</p> <p>24 to confounding or bias.</p> <p>25 So I would say, you know,</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. MURDICA: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: Again --</p> <p>4 MR. MURDICA: Go ahead and</p> <p>5 answer.</p> <p>6 THE WITNESS: Sorry. I think I</p> <p>7 answer too quickly.</p> <p>8 Again, that's an impossible</p> <p>9 question to answer in that sort of</p> <p>10 theoretical framework. It is very</p> <p>11 dependent upon the literature that</p> <p>12 you're reviewing, the specifics of the</p> <p>13 studies. Statistically significant</p> <p>14 results can be due to all kinds of</p> <p>15 bias and confounding, obviously, and</p> <p>16 they can also relate to a whole range</p> <p>17 of outcomes, which is important to</p> <p>18 consider when you're looking at the</p> <p>19 number of statistically significant</p> <p>20 associations.</p> <p>21 So I can't answer that</p> <p>22 question.</p> <p>23 QUESTIONS BY MR. SNIDOW:</p> <p>24 Q. So I think maybe you</p> <p>25 misunderstood. I'm not asking about</p>
<p style="text-align: right;">Page 47</p> <p>1 there's not a precise number there.</p> <p>2 I'm not willing to give you a precise</p> <p>3 number because it depends so much on</p> <p>4 the context.</p> <p>5 QUESTIONS BY MR. SNIDOW:</p> <p>6 Q. That's what I was asking.</p> <p>7 It's not 2.0, 3.0. You can't</p> <p>8 do it like that?</p> <p>9 A. That's not how I do it.</p> <p>10 Q. You think it would be wrong to</p> <p>11 just set a cutoff, right? Because you have</p> <p>12 to consider all of the data, right?</p> <p>13 MR. MURDICA: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I think different</p> <p>16 epidemiologists and biostatisticians</p> <p>17 approach the question differently.</p> <p>18 The way I approach it is that there's</p> <p>19 not a right number that you need to</p> <p>20 exceed.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. Okay. How many statistically</p> <p>23 significant results do you need before you</p> <p>24 think there's an association that's been</p> <p>25 demonstrated?</p>	<p style="text-align: right;">Page 49</p> <p>1 causation.</p> <p>2 I'm just saying, how many</p> <p>3 results before you would say there's an</p> <p>4 association? Maybe it's confounding, maybe</p> <p>5 it's bias, but I think there's an</p> <p>6 association.</p> <p>7 A. Again, I can't give you a</p> <p>8 number. It's dependent upon the underlying</p> <p>9 data.</p> <p>10 Q. So if I had 500 studies showing</p> <p>11 a statistically significant link between an</p> <p>12 exposure and an outcome, you'd say, "I don't</p> <p>13 know if there's an association"?</p> <p>14 MR. MURDICA: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: Again --</p> <p>17 MR. MURDICA: Go ahead.</p> <p>18 THE WITNESS: I can't answer</p> <p>19 that in this theoretical context. I</p> <p>20 would want to look at the studies. I</p> <p>21 would understand -- I want to</p> <p>22 understand how the data was derived.</p> <p>23 You could have 500 statistically</p> <p>24 significant studies that were wrong</p> <p>25 because they were all confounded.</p>

<p style="text-align: right;">Page 50</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. I agree. That's not what I'm</p> <p>3 asking. So put aside confounding.</p> <p>4 Can you do that for me?</p> <p>5 MR. MURDICA: Objection to</p> <p>6 form.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Can you put aside confounding?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 Answer the --</p> <p>12 THE WITNESS: I will -- I will</p> <p>13 ignore the idea of confounding to</p> <p>14 answer your question.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. And bias, okay, ignore that.</p> <p>17 All I'm asking is, for an</p> <p>18 association, if I had 500 studies showing a</p> <p>19 statistically significant link, that would be</p> <p>20 an association, right?</p> <p>21 It doesn't mean it's causal,</p> <p>22 but that would be an association, right?</p> <p>23 MR. MURDICA: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: So you've asked</p>	<p style="text-align: right;">Page 52</p> <p>1 know.</p> <p>2 All right. So I made up these</p> <p>3 numbers. But can you tell me on this forest</p> <p>4 plot what study 1 is showing?</p> <p>5 MR. MURDICA: I object to the</p> <p>6 use of this, but you can answer it, if</p> <p>7 you can.</p> <p>8 THE WITNESS: It says a 1.5</p> <p>9 something. I don't know. There's</p> <p>10 no --</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. And that is a relative risk.</p> <p>13 A. Okay. So you're telling me</p> <p>14 those top numbers are relative risk?</p> <p>15 Q. Yes.</p> <p>16 A. So it shows you that there's a</p> <p>17 1 point -- something like 1.5, 1.6 relative</p> <p>18 risk with a confidence interval that goes</p> <p>19 from something like 1.25 to 1 point -- to</p> <p>20 almost 2.0.</p> <p>21 Q. Okay. Is that result</p> <p>22 statistically significant?</p> <p>23 A. This -- I have no idea what</p> <p>24 this -- what this means in statistical terms.</p> <p>25 If you had this in a textbook, it would show</p>
<p style="text-align: right;">Page 51</p> <p>1 me to ignore two things that are</p> <p>2 absolutely central to observational</p> <p>3 studies. So you're asking me</p> <p>4 something that's theoretically</p> <p>5 impossible. There's no such thing as</p> <p>6 an observational study that is free of</p> <p>7 bias and confounding, so I can't</p> <p>8 answer the question.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Okay. How do you define a</p> <p>11 causal agent?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: A causal agent is</p> <p>15 something for which there is</p> <p>16 consistent, reliable, valid evidence</p> <p>17 that the dose of that agent, if you</p> <p>18 will, increases the risk of the</p> <p>19 outcome that you're studying.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. You know what a forest plot is,</p> <p>22 right?</p> <p>23 A. I do.</p> <p>24 Q. All right. I'm going to do one</p> <p>25 as an example. I would mark it, but, you</p>	<p style="text-align: right;">Page 53</p> <p>1 that this is evidence of a statistically</p> <p>2 significant effect, but it's completely</p> <p>3 without context here, so...</p> <p>4 Q. I know. I'm just -- I promise,</p> <p>5 I made these up. I'm truly just trying to</p> <p>6 talk about concepts.</p> <p>7 For study 2, essentially same</p> <p>8 thing, except the point estimate is somewhere</p> <p>9 around 2.3; is that right?</p> <p>10 A. That looks about right.</p> <p>11 Q. Right.</p> <p>12 And it is statistically</p> <p>13 significant, right?</p> <p>14 A. Again, the confidence intervals</p> <p>15 do not include 1.</p> <p>16 Q. Study 3, the point estimate</p> <p>17 looks like maybe 1.2?</p> <p>18 A. Maybe 1.1.</p> <p>19 Q. Yeah, maybe 1.1.</p> <p>20 And that one is not</p> <p>21 statistically significant, right?</p> <p>22 A. Confidence intervals include 1,</p> <p>23 which would indicate that you cannot rule out</p> <p>24 chance as an explanation for that --</p> <p>25 Q. Okay.</p>

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1 A. -- whatever it is.

2 Q. Yeah.

3 All right. And then the last

4 one there, study 8, similar point estimate,

5 but the confidence intervals are wider,

6 right?

7 A. Correct.

8 Q. Okay. And it's not

9 statistically significant, right?

10 A. Confidence intervals include 1.

11 Q. Would you -- would you

12 characterize this as a strong association?

13 MR. MURDICA: Objection to

14 form.

15 THE WITNESS: I cannot answer

16 that question.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Okay.

19 A. Because without the context of

20 the underlying data, I have no way of judging

21 whether it's strong or not.

22 Q. How about a consistent

23 association? Would you say this is

24 consistent?

25 A. I would say the same thing for

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1 consistency. Without understanding how these

2 results were derived --

3 Q. Yeah.

4 A. -- I cannot determine whether

5 there's consistency.

6 Q. The only reason I ask is

7 because in your report, if I read it

8 correctly, you suggest that the presence of

9 statistically nonsignificant findings means

10 that the results can't be consistent; is that

11 right?

12 MR. MURDICA: Objection to

13 form.

14 THE WITNESS: In my report, I

15 state that statistical significance is

16 relevant to my consideration for

17 consistency. It is not the only

18 criterion by which I judge

19 consistency.

20 But I certainly take that into

21 account when I'm looking to see

22 whether a body of literature has

23 consistent results.

24 QUESTIONS BY MR. SNIDOW:

25 Q. Let me ask it a different way.

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1 Can a set of results ever be

2 consistent if some of the confidence

3 intervals overlap with 1?

4 MR. MURDICA: Objection to

5 form.

6 THE WITNESS: It depends on

7 your definition of consistency. The

8 way I derive consistency, it includes

9 an evaluation of the statistical

10 significance of the results and a

11 whole host of other things, which I'm

12 happy to talk to you about.

13 QUESTIONS BY MR. SNIDOW:

14 Q. But can you answer my question?

15 Can a set of results ever be statistically

16 significant if -- sorry, strike it.

17 Can a set of results ever be

18 consistent if some of the results are not

19 statistically significant?

20 MR. MURDICA: Same objection.

21 THE WITNESS: I cannot answer

22 that question in a theoretical context

23 like that. I would need to know

24 exactly what you're talking about. I

25 would need to understand the

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1 underlying data. I can't do it --

2 QUESTIONS BY MR. SNIDOW:

3 Q. Okay.

4 A. -- in isolation.

5 Q. All right. But on this one, I

6 want to talk about this result, study 7.

7 This is showing a point

8 estimate below 1?

9 A. Correct.

10 Q. What's that indicate?

11 A. Well, in most cases, depending

12 on what these data mean, that is a protective

13 effect of the exposure on the outcome.

14 Q. And that one is statistically

15 significant as well, right?

16 A. It shows a statistically

17 significant protective effect for whatever it

18 is. Again, without any knowledge of the

19 underlying data, that's, you know, hard to

20 say.

21 Q. Okay. All right. You know

22 what a prospective cohort study is?

23 A. I do.

24 Q. And so the way those work is

25 you identify a group of unexposed and exposed

<p style="text-align: right;">Page 58</p> <p>1 groups, right?</p> <p>2 A. Typically that's the way you</p> <p>3 enroll individuals into a prospective cohort</p> <p>4 study.</p> <p>5 Q. And then you follow them over</p> <p>6 time to see which ones develop the outcome of</p> <p>7 interest?</p> <p>8 A. That's right.</p> <p>9 Q. And if the same percentage</p> <p>10 develop the outcome of interest, that's</p> <p>11 equivalent to a risk ratio of 1.0?</p> <p>12 MR. MURDICA: Note my objection</p> <p>13 to the use of the demonstrative.</p> <p>14 MR. SNIDOW: Got it. Got it.</p> <p>15 MR. MURDICA: And object to the</p> <p>16 form of the question.</p> <p>17 QUESTIONS BY MR. SNIDOW:</p> <p>18 Q. If the same percentage develop</p> <p>19 the outcome, it's equivalent to a risk of</p> <p>20 1.0?</p> <p>21 A. Again, you know, this is --</p> <p>22 these are such sort of theoretical concepts.</p> <p>23 Q. Okay.</p> <p>24 A. But, yes, theoretically, that's</p> <p>25 the way it works.</p>	<p style="text-align: right;">Page 60</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Right.</p> <p>3 There's only one more person</p> <p>4 that got the outcome of interest in the</p> <p>5 exposed, right?</p> <p>6 A. Right.</p> <p>7 Q. All right. So null finding</p> <p>8 again.</p> <p>9 So but you would agree if -- I</p> <p>10 did 100 kids here, but if these actually</p> <p>11 represented a million kids in each arm, that</p> <p>12 could still be a statistically significant</p> <p>13 result, right?</p> <p>14 MR. MURDICA: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: I would want to</p> <p>17 do the numbers and understand what we</p> <p>18 were talking about in terms of</p> <p>19 exposure. I would want to know how</p> <p>20 that exposure was ascertained. I</p> <p>21 would want to know the reliability and</p> <p>22 the validity of that exposure.</p> <p>23 I cannot answer a question, you</p> <p>24 know, like whether it would be</p> <p>25 significant or important without the</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. Okay. And so if you see</p> <p>2 something like this, that doesn't give you a</p> <p>3 signal one way or another, does it?</p> <p>4 MR. MURDICA: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: I would say</p> <p>7 that's a null finding.</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. Right.</p> <p>10 Exactly a null finding. It's</p> <p>11 1.0 on the dot.</p> <p>12 A. Perfect.</p> <p>13 Q. Yeah, perfect.</p> <p>14 A. A perfect finding.</p> <p>15 Q. And even if there are, you</p> <p>16 know, tiny differences between the groups</p> <p>17 like this, still probably a null finding.</p> <p>18 You'd have to do the math, but probably a</p> <p>19 null finding, right?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: Again, really</p> <p>23 hard to say just based on a chart like</p> <p>24 this, but I don't see a big difference</p> <p>25 between those two groups.</p>	<p style="text-align: right;">Page 61</p> <p>1 context.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Well, you can for the</p> <p>4 statistical significance, right? You can</p> <p>5 just run the math.</p> <p>6 MR. MURDICA: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: Again,</p> <p>9 statistical significance depends on</p> <p>10 the quality of the data underlying it.</p> <p>11 You can have a statistically</p> <p>12 significant result that is flawed</p> <p>13 because the underlying data is biased.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. I totally agree. And that's</p> <p>16 why I say, please set that aside. I'm just</p> <p>17 saying --</p> <p>18 A. It's very hard to do.</p> <p>19 Q. No, I know, but for the numbers</p> <p>20 it's not, right?</p> <p>21 You could run the math and see</p> <p>22 whether these are statistically significant</p> <p>23 differences, right?</p> <p>24 MR. MURDICA: Object to form.</p> <p>25</p>

<p style="text-align: right;">Page 62</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Is that right?</p> <p>3 MR. MURDICA: Note my</p> <p>4 objection.</p> <p>5 MR. SNIDOW: Yeah. I got -- I</p> <p>6 got the objection --</p> <p>7 MR. MURDICA: I can't --</p> <p>8 MR. SNIDOW: Ah-ah-ah, you</p> <p>9 promised. You promised.</p> <p>10 MR. MURDICA: I can't sit here</p> <p>11 forever with you asking the same</p> <p>12 question with the -- with this made-up</p> <p>13 thing.</p> <p>14 MR. SNIDOW: Jim? Jim, we</p> <p>15 talked in the hallway. You promised.</p> <p>16 MR. MURDICA: Okay. But you</p> <p>17 still have to conduct yourself in</p> <p>18 accordance with the rules.</p> <p>19 MR. SNIDOW: Okay.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. Ma'am, is that right, you can</p> <p>22 run the math and determine whether or not</p> <p>23 these are statistically significant?</p> <p>24 A. I would say you could run a</p> <p>25 mathematical equation to determine the</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Are you asking me whether I</p> <p>2 agree with you?</p> <p>3 Q. I'm asking, yeah. Is that</p> <p>4 right?</p> <p>5 A. So again, I --</p> <p>6 mathematically that is a correct analysis.</p> <p>7 It is meaningless without the context of the</p> <p>8 underlying data.</p> <p>9 Q. Okay. And this is a risk ratio</p> <p>10 of 1.2, right -- or sorry, 2.0?</p> <p>11 MR. MURDICA: Objection to</p> <p>12 form.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. Is that right?</p> <p>15 A. Again, mathematically if you</p> <p>16 were to run these numbers, I believe you</p> <p>17 would come up with a risk ratio of 2.0. It</p> <p>18 is meaningless without the underlying</p> <p>19 context.</p> <p>20 Q. That's a doubling of the risk?</p> <p>21 A. 2.0 is equivalent of the</p> <p>22 doubling of the risk.</p> <p>23 Q. Also known as 100 percent</p> <p>24 increase in the risk, right?</p> <p>25 A. That is also referred to as</p>
<p style="text-align: right;">Page 63</p> <p>1 relative risk in this, you know, artificial</p> <p>2 example, but it's meaningless in my mind</p> <p>3 without the underlying context.</p> <p>4 Q. Sure.</p> <p>5 This is equivalent to a</p> <p>6 relative risk of 1.5?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Do you want me to</p> <p>10 count them?</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Yeah. I promise, it's -- it's</p> <p>13 25 in the exposed and 20 in the unexposed.</p> <p>14 Oh, sorry. It's 30 in the exposed and 20 in</p> <p>15 the unexposed.</p> <p>16 A. I'm sorry, so what's the</p> <p>17 question?</p> <p>18 Q. Risk ratio is 1.5.</p> <p>19 MR. MURDICA: Objection to</p> <p>20 form.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. Is that right?</p> <p>23 A. Are you asking me or telling</p> <p>24 me? You just told me.</p> <p>25 Q. I'm --</p>	<p style="text-align: right;">Page 65</p> <p>1 100 percent increase in the risk.</p> <p>2 Q. And as you said before, as the</p> <p>3 risk ratio increases, the likelihood of a</p> <p>4 chance finding goes down?</p> <p>5 MR. MURDICA: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: So in general,</p> <p>8 that is the way we think about it.</p> <p>9 The larger the risk, the less likely</p> <p>10 it is to be explained away by bias and</p> <p>11 confounding.</p> <p>12 It does not mean it's</p> <p>13 impossible to explain it away by bias</p> <p>14 and confounding. I think that's very</p> <p>15 important to consider here.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. That actually wasn't my</p> <p>18 question. That was going to be my next one.</p> <p>19 My question was, as the risk</p> <p>20 ratio increases, the likelihood of a chance</p> <p>21 finding goes down?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: So chance is one</p> <p>25 of the things that we worry about in</p>

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1 terms of statistical significance, and
 2 we can never absolutely determine
 3 whether we can rule out chance as an
 4 explanation because we have typically
 5 one study that we're relying on.
 6 And we're saying, does the
 7 evidence from this study overwhelm
 8 the possibility that chance explains
 9 the finding. We could be wrong.
 10 QUESTIONS BY MR. SNIDOW:
 11 Q. Okay. Do you remember my
 12 question, though?
 13 MR. MURDICA: Objection to
 14 form.
 15 QUESTIONS BY MR. SNIDOW:
 16 Q. Do you remember it?
 17 A. I thought I answered it. I'm
 18 sorry.
 19 Q. My question was, as the risk
 20 ratio increases, the likelihood of a chance
 21 finding goes down?
 22 I know it's not zero, but the
 23 likelihood goes down, right?
 24 MR. MURDICA: Objection to
 25 form.

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1 THE WITNESS: I think that
 2 that, again, is very hard to state,
 3 you know, a definitive answer to in
 4 the absence of context.
 5 QUESTIONS BY MR. SNIDOW:
 6 Q. Okay. All right. If you had a
 7 study like this, this doubling of the risk in
 8 the exposed group, you would agree and you
 9 said, the options are it could be -- it could
 10 be chance, right? Is that right?
 11 A. Yeah.
 12 Q. It could be bias?
 13 A. Uh-huh.
 14 Q. And do some epidemiologists say
 15 that confounding's a type of bias?
 16 A. That's fine. I can -- I can
 17 accept that.
 18 Q. But I'll say it, it can be
 19 confounding?
 20 A. It can be confounding.
 21 Q. And the remaining option is
 22 causation, right?
 23 MR. MURDICA: Objection to
 24 form.
 25 THE WITNESS: If you rule out

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1 all of the others, then you have
 2 evidence in support of a causal
 3 association.
 4 I wouldn't say you've
 5 established causation. I think
 6 there's a difference in the way I
 7 phrased that that's an important one.
 8 QUESTIONS BY MR. SNIDOW:
 9 Q. Helpful.
 10 My question, though, is, are
 11 there other theoretical possibilities for
 12 what's going on here besides chance, bias,
 13 confounding and causation?
 14 MR. MURDICA: Objection to the
 15 form and the continued use of this
 16 hypothetical demonstrative.
 17 THE WITNESS: In standard
 18 epidemiologic textbook explanation,
 19 no.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. All right. That's where I got
 22 it from, so thank you.
 23 Oh, and actually, I'll just say
 24 it. This is basically how the link between
 25 tobacco and lung cancer was detected, right?

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1 They noticed that people exposed to tobacco
 2 had much higher risks of lung cancer?
 3 MR. MURDICA: Objection to
 4 form.
 5 THE WITNESS: So the history of
 6 the association between tobacco and
 7 lung cancer goes way back. There are
 8 hundreds, possibly thousands, of
 9 studies that involve all different
 10 kinds of study design. A prospective
 11 cohort study would certainly be one of
 12 those.
 13 There are case-control studies.
 14 There are ecological studies. There
 15 are all kinds of pieces of evidence
 16 that support the notion of a causal
 17 link.
 18 QUESTIONS BY MR. SNIDOW:
 19 Q. Right.
 20 But -- I totally agree. But
 21 I'm just asking, they originally detected the
 22 link, originally in the '20s through the
 23 '60s, by looking at people who were exposed
 24 to tobacco versus people who weren't, right?
 25 A. That's correct.

<p style="text-align: right;">Page 70</p> <p>1 Q. And they noticed the people who</p> <p>2 were had a much higher rate?</p> <p>3 A. That's correct.</p> <p>4 Q. And then they ruled out bias</p> <p>5 and confounding and chance, right?</p> <p>6 MR. MURDICA: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: Over time those</p> <p>9 were ruled out.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. Over time.</p> <p>12 And that's how they made the</p> <p>13 causal inference, right?</p> <p>14 A. I agree.</p> <p>15 Q. That's what the Surgeon General</p> <p>16 did?</p> <p>17 A. I agree.</p> <p>18 Q. Okay. In your report you state</p> <p>19 your belief that ASD is primarily caused by</p> <p>20 genetics; is that right?</p> <p>21 A. That's right.</p> <p>22 Q. And you think genetics are a</p> <p>23 primary cause of ADHD as well?</p> <p>24 A. I do.</p> <p>25 Q. Do you agree that the</p>	<p style="text-align: right;">Page 72</p> <p>1 THE WITNESS: Some diseases,</p> <p>2 certainly.</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. Down syndrome is a good</p> <p>5 example?</p> <p>6 A. Yes.</p> <p>7 Q. Identical twins will either</p> <p>8 both have Down syndrome or neither have Down</p> <p>9 syndrome, excluding some rare mosaic cases,</p> <p>10 right?</p> <p>11 A. I don't know the genetics of</p> <p>12 Down syndrome, but that would make sense to</p> <p>13 me if it's a single gene disorder and they're</p> <p>14 identical twins that have the same set of</p> <p>15 genes.</p> <p>16 Q. Well, you know it's a</p> <p>17 replication of the 23rd chromosome?</p> <p>18 A. Uh-huh.</p> <p>19 Q. And that's something that</p> <p>20 happens at conception?</p> <p>21 A. Uh-huh.</p> <p>22 Q. Immediately, right?</p> <p>23 MR. MURDICA: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: Again, I'm not an</p>
<p style="text-align: right;">Page 71</p> <p>1 heritability for ASD and ADHD is not</p> <p>2 100 percent?</p> <p>3 A. I do.</p> <p>4 Q. And that means that</p> <p>5 environmental factors play a role, right?</p> <p>6 A. That means that factors other</p> <p>7 than those that are passed down from the</p> <p>8 mother and father to the fetus could have an</p> <p>9 influence. We don't know, but that's</p> <p>10 possible.</p> <p>11 Q. Okay. Including environmental</p> <p>12 factors?</p> <p>13 A. So, yes. Environmental factors</p> <p>14 I would describe as anything other than</p> <p>15 genetic factors.</p> <p>16 And so that would include</p> <p>17 lifestyle factors. That would include</p> <p>18 de novo mutations that are not passed down</p> <p>19 from the mother and father but that are</p> <p>20 genetic in origin. And it would include</p> <p>21 things in the environment.</p> <p>22 Q. You agree there are some</p> <p>23 diseases that are entirely genetic, right?</p> <p>24 MR. MURDICA: Objection to</p> <p>25 form.</p>	<p style="text-align: right;">Page 73</p> <p>1 embryologist, but...</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Okay. Well, you don't -- I</p> <p>4 mean, do you not know that Down syndrome</p> <p>5 is -- occurs initially when the egg is</p> <p>6 fertilized?</p> <p>7 A. I do know that.</p> <p>8 Q. And that -- that's the</p> <p>9 monozygotic egg, right?</p> <p>10 A. Yes.</p> <p>11 Q. So when it splits, they're</p> <p>12 either both going to have Down's or neither</p> <p>13 is, right?</p> <p>14 A. A single gene disorder, that's</p> <p>15 how it works.</p> <p>16 Q. And autism is not like that, is</p> <p>17 it?</p> <p>18 A. No.</p> <p>19 Q. No.</p> <p>20 You agree that autism is not</p> <p>21 caused entirely by genetics, true?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: As we said,</p> <p>25 heritability is not 1 or 100 percent,</p>

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1 however you prefer to speak of it, so
 2 there are other factors.
 3 QUESTIONS BY MR. SNIDOW:
 4 Q. Okay. The reason you know
 5 that, in part, is because the concordance for
 6 monozygotic twins for autism, it's not
 7 100 percent, is it?
 8 A. Correct.
 9 Q. And what's the -- I know the
 10 estimates keep changing.
 11 What do you think the best
 12 estimate for that is now?
 13 A. Heritability?
 14 Q. No, for the concordance of
 15 monozygotic twins.
 16 A. I would say around 90 percent,
 17 but, again, it varies depending on who's
 18 doing the study.
 19 Q. So it's -- basically, that
 20 estimate has stayed the same for the last ten
 21 years or so?
 22 A. It's bounced around a little
 23 bit, but yes.
 24 Q. And outside of some rare cases,
 25 like Fragile X, you agree there's no single

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1 gene for autism?
 2 A. There's no single gene for
 3 autism, right.
 4 Q. You've never counseled someone
 5 to get genetic counseling if they had a child
 6 with autism?
 7 MR. MURDICA: Objection to
 8 form.
 9 THE WITNESS: So I'm not a
 10 geneticist, and I don't counsel
 11 patients. So I'm not going to opine
 12 on that.
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. Oh, you wouldn't take a
 15 position on that?
 16 A. I'm not -- it's not my area of
 17 expertise.
 18 Q. So if someone asked you whether
 19 you'd counsel someone to get genetic testing,
 20 you'd say, "I can't take a position on that"?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: I would say I'm
 24 not a geneticist, and I don't counsel
 25 patients, so I wouldn't try to do

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1 that.
 2 MR. SNIDOW: Can we play tab
 3 NN? And I've still got the ELMO.
 4 Do you want to go off the
 5 record, Michael?
 6 MICHAEL KAUFFMANN: Yeah.
 7 MR. SNIDOW: Okay. Go off the
 8 record.
 9 VIDEOGRAPHER: The time is
 10 9:28 a.m. We're off the record.
 11 (Off the record at 9:28 a.m.)
 12 VIDEOGRAPHER: The time is
 13 9:32 a.m., and we're on the record.
 14 MR. MURDICA: Okay. I would
 15 just like to ask that this is twice
 16 now that plaintiff's counsel has
 17 unilaterally gone off the record. I
 18 asked off the record respectfully that
 19 there be consent to do that or at
 20 least a discussion in the future.
 21 So this is my notation on the
 22 record that that's my request.
 23 Thank you.
 24 MR. SNIDOW: That's fine. All
 25 right. Can you play NN?

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1 (Video played.)
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. All right. Dr. Pinto-Martin,
 4 is that you?
 5 A. That is.
 6 Q. All right. And that was in
 7 about 2014, I think?
 8 MR. MURDICA: Objection to
 9 form.
 10 THE WITNESS: That's probably
 11 about right.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. And she asked you whether you'd
 14 counsel someone to get genetic testing,
 15 right?
 16 A. I can't remember precisely what
 17 her question is, but that's what we were
 18 talking about.
 19 Q. Do you want to play it again?
 20 A. No, I mean --
 21 Q. Okay.
 22 A. Yeah.
 23 Q. And you didn't say, "Oh, I
 24 can't say anything about that," right? You
 25 just said no; is that right?

<p style="text-align: right;">Page 78</p> <p>1 MR. MURDICA: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: I didn't just say</p> <p>4 no. I described what I think about in</p> <p>5 terms of the value of genetic testing.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. In that clip, did you ever say,</p> <p>8 "Oh, I can't talk about that"?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: Again, this was a</p> <p>12 discussion about the value of genetic</p> <p>13 testing. I would still -- had she</p> <p>14 asked me, "Do you individually counsel</p> <p>15 patients," I would have said no. The</p> <p>16 situation does not change.</p> <p>17 MR. MURDICA: Do you have the</p> <p>18 entire video? Sorry.</p> <p>19 MR. SNIDOW: Yeah.</p> <p>20 MR. MURDICA: I don't want to</p> <p>21 interrupt the question.</p> <p>22 MR. SNIDOW: We'll send it to</p> <p>23 you.</p> <p>24 MR. MURDICA: Well, look, if</p> <p>25 you're going to ask her about the</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Okay.</p> <p>2 MR. SNIDOW: Let's look at tab</p> <p>3 LL.</p> <p>4 (Video played.)</p> <p>5 MR. MURDICA: Okay. Before you</p> <p>6 ask a question, if this were -- if you</p> <p>7 were cross-examining via prior sworn</p> <p>8 testimony, like a deposition</p> <p>9 transcript, you'd have to show the</p> <p>10 entire transcript when you were</p> <p>11 cross-examining.</p> <p>12 Instead, you're taking little</p> <p>13 video clips without the whole context,</p> <p>14 which I don't think is proper</p> <p>15 examination, and so I object.</p> <p>16 I don't actually think you can</p> <p>17 do this, J.J.</p> <p>18 MR. SNIDOW: Okay. Are you</p> <p>19 done?</p> <p>20 MR. MURDICA: I'm trying to</p> <p>21 decide if --</p> <p>22 MR. SNIDOW: Yeah. We can go</p> <p>23 off the record and call the judge.</p> <p>24 MR. MURDICA: All right. Is</p> <p>25 this your last one, or do you have a</p>
<p style="text-align: right;">Page 79</p> <p>1 whole thing, if you're going to say</p> <p>2 "you never said this," I think she's</p> <p>3 got to see the whole thing.</p> <p>4 MR. SNIDOW: That's fair.</p> <p>5 That's fair. That's fair.</p> <p>6 MR. MURDICA: So don't ask any</p> <p>7 more questions like that.</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. Do you agree that you need an</p> <p>10 environmental trigger in addition to genetics</p> <p>11 to actually trigger the autism?</p> <p>12 A. I don't believe we know the</p> <p>13 answer to that. So we know that it's highly</p> <p>14 heritable, and we know that there are some</p> <p>15 other factors that matter, but those other</p> <p>16 factors might also be related to genetics.</p> <p>17 Q. But you don't -- you wouldn't</p> <p>18 agree that you need an environmental trigger</p> <p>19 in addition to genetics?</p> <p>20 A. I think that was the thought --</p> <p>21 Q. Uh-huh.</p> <p>22 A. -- in the past, and I think</p> <p>23 that I have -- my thinking has evolved since</p> <p>24 then, and I don't know that we need an</p> <p>25 environmental, quote/unquote, trigger.</p>	<p style="text-align: right;">Page 81</p> <p>1 lot of these?</p> <p>2 MR. SNIDOW: It's on YouTube.</p> <p>3 Go YouTube it. Okay? Are you done?</p> <p>4 MR. MURDICA: But you would</p> <p>5 need to examine with the entire thing.</p> <p>6 MR. SNIDOW: All I'm asking is</p> <p>7 whether we're calling -- I'm not going</p> <p>8 to play a 40-minute video in the</p> <p>9 deposition, obviously. We'll send you</p> <p>10 the YouTube link if you don't have it,</p> <p>11 although I suspect you do.</p> <p>12 MR. MURDICA: I don't have it.</p> <p>13 MR. SNIDOW: Okay. Well, are</p> <p>14 we going to call the judge, or are we</p> <p>15 going to go on?</p> <p>16 MR. MURDICA: Are you to going</p> <p>17 ask a question about the entire</p> <p>18 conversation?</p> <p>19 MR. SNIDOW: I'm going to ask</p> <p>20 her a question.</p> <p>21 MR. MURDICA: All right. Let's</p> <p>22 hear it.</p> <p>23 QUESTIONS BY MR. SNIDOW:</p> <p>24 Q. My question is, is that you,</p> <p>25 Dr. Pinto-Martin?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. That's still me.</p> <p>2 Q. Okay. And I noticed in there</p> <p>3 that it said that the concordance for twins</p> <p>4 was 65 or 70.</p> <p>5 Is that dated data?</p> <p>6 A. So you yourself pointed out</p> <p>7 this was in about 2014.</p> <p>8 Q. Yeah.</p> <p>9 A. So, yes, our knowledge has</p> <p>10 evolved.</p> <p>11 Q. That's all I was asking.</p> <p>12 It's still not 100 percent,</p> <p>13 though, right?</p> <p>14 A. Correct.</p> <p>15 Q. And you did say in there that</p> <p>16 you need an environmental trigger in addition</p> <p>17 to the genetics to actually trigger the</p> <p>18 autism, right?</p> <p>19 MR. MURDICA: Object to form.</p> <p>20 THE WITNESS: I said that in</p> <p>21 2014 based on our best evidence at</p> <p>22 that time.</p> <p>23 QUESTIONS BY MR. SNIDOW:</p> <p>24 Q. And since 2014, has the</p> <p>25 concordance for identical twins gone to</p>	<p style="text-align: right;">Page 84</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Do you think that the things</p> <p>3 that happen in utero is where you should look</p> <p>4 to find causes of autism?</p> <p>5 A. I think genetics is where you</p> <p>6 should look to find causes of autism. I</p> <p>7 think 90 percent of autism is explainable by</p> <p>8 heritable factors. That's a huge proportion.</p> <p>9 Q. And the other 10 percent?</p> <p>10 MR. MURDICA: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: The other</p> <p>13 10 percent we don't know.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Okay.</p> <p>16 A. And the other 10 percent could,</p> <p>17 in fact, be tied to genetic factors. So</p> <p>18 we're, as I said, exploring very intensely to</p> <p>19 understand what the risk factors are and we</p> <p>20 don't have the answers yet.</p> <p>21 MR. SNIDOW: Let's play tab KK.</p> <p>22 (Video played.)</p> <p>23 QUESTIONS BY MR. SNIDOW:</p> <p>24 Q. You said that, right?</p> <p>25 A. I said that.</p>
<p style="text-align: right;">Page 83</p> <p>1 100 percent?</p> <p>2 A. As we have already discussed,</p> <p>3 it's not 100 percent. It's closer to</p> <p>4 90 percent.</p> <p>5 Q. Do you agree that there are</p> <p>6 things that happen to the fetus in utero that</p> <p>7 predispose a child to autism?</p> <p>8 A. I don't think we know the</p> <p>9 specifics of intrauterine effects on the</p> <p>10 fetus that might cause autism. We are very</p> <p>11 interested in studying what those effects</p> <p>12 might be, but I would say we're still in the</p> <p>13 early stages of understanding what those</p> <p>14 factors might be.</p> <p>15 Q. Do you think the most important</p> <p>16 place to look when searching for causes of</p> <p>17 autism is the gestational period?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I believe that</p> <p>21 autism is a congenital disorder so</p> <p>22 that the effect happens in utero. We</p> <p>23 can't detect it right away, but a</p> <p>24 child is born with or without autism.</p> <p>25</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. And you referred to causal</p> <p>2 agents in that video, right?</p> <p>3 MR. MURDICA: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: I think I used</p> <p>6 that terminology, yes.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. In utero causal agents, right?</p> <p>9 A. And this was in 2014.</p> <p>10 Q. Do you agree that prenatal</p> <p>11 environmental exposures can alter the brain?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: I'd like you to</p> <p>15 cite something specific. That's a</p> <p>16 very general statement. I think</p> <p>17 there -- there can be evidence, but I</p> <p>18 would like you to be specific.</p> <p>19 (Pinto-Martin Exhibit 602</p> <p>20 marked for identification.)</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. Okay. Can I have tab AAA also?</p> <p>23 Yeah. And also that second book.</p> <p>24 All right. You've seen this</p> <p>25 before?</p>

<p style="text-align: right;">Page 86</p> <p>1 A. Uh-huh.</p> <p>2 Q. Okay. Did you write a chapter</p> <p>3 in this book?</p> <p>4 A. I was part of a team that wrote</p> <p>5 a chapter for that book.</p> <p>6 Q. Okay. So here's what I'm going</p> <p>7 to do. I excerpted the entire chapter here.</p> <p>8 A. Okay.</p> <p>9 MR. SNIDOW: Jim, if you'd like</p> <p>10 the whole book, be my guest.</p> <p>11 MR. MURDICA: Thank you.</p> <p>12 MR. SNIDOW: And I'm going to</p> <p>13 mark this one as 602.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. All right. And on the first</p> <p>16 page, that's your name, Jennifer</p> <p>17 Pinto-Martin?</p> <p>18 A. Correct.</p> <p>19 Q. And you wrote or co-authored</p> <p>20 this chapter?</p> <p>21 A. I did.</p> <p>22 Q. And on 499 at the bottom, do</p> <p>23 you see where it says "Ongoing research"?</p> <p>24 A. At the very bottom, yeah.</p> <p>25 Q. It says, "Ongoing research is</p>	<p style="text-align: right;">Page 88</p> <p>1 THE WITNESS: It does alter pre</p> <p>2 or postnatal brain development alone</p> <p>3 or by altering gene actions, yeah.</p> <p>4 QUESTIONS BY MR. SNIDOW:</p> <p>5 Q. Okay. And what that's saying</p> <p>6 is prenatal environmental exposures can alter</p> <p>7 the brain.</p> <p>8 MR. MURDICA: Objection to</p> <p>9 form.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. Is that right?</p> <p>12 A. As I said, I think that's a</p> <p>13 hypothesis that we are putting forth in this</p> <p>14 chapter.</p> <p>15 By the way, can you tell me the</p> <p>16 date of this? I don't remember when we</p> <p>17 authored this, but it was a while ago.</p> <p>18 Q. I don't --</p> <p>19 MR. MURDICA: I can.</p> <p>20 MR. SNIDOW: Jim took the book.</p> <p>21 MR. MURDICA: It looks like</p> <p>22 15 years ago.</p> <p>23 MR. SNIDOW: Can you just give</p> <p>24 the date, Jim?</p> <p>25 MR. MURDICA: '08.</p>
<p style="text-align: right;">Page 87</p> <p>1 examining the role of hormones, infection,</p> <p>2 autoimmune response, exogenous toxic</p> <p>3 exposures, and other potential environmental</p> <p>4 influences that might alter pre or postnatal</p> <p>5 brain development alone or by altering gene</p> <p>6 action."</p> <p>7 Is that right?</p> <p>8 A. I think my --</p> <p>9 Q. It skips over to 501.</p> <p>10 A. Yeah, I can't read the top of</p> <p>11 501 because it's highlighted and then</p> <p>12 highlighted again.</p> <p>13 MR. MURDICA: It's highlighted</p> <p>14 and copied and blacked out.</p> <p>15 THE WITNESS: Yeah, it's like</p> <p>16 really dark. I can't -- I mean, I</p> <p>17 believe you if you say that's what it</p> <p>18 says, but it would be better to have a</p> <p>19 clean copy.</p> <p>20 MR. MURDICA: I'll give you</p> <p>21 mine.</p> <p>22 THE WITNESS: That's also</p> <p>23 pretty hard to see, but --</p> <p>24 MR. SNIDOW: You can't read</p> <p>25 that?</p>	<p style="text-align: right;">Page 89</p> <p>1 MR. SNIDOW: Thank you.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. All right. You can put that</p> <p>4 aside.</p> <p>5 Do you agree that there are</p> <p>6 environmental factors that can cause autism?</p> <p>7 MR. MURDICA: Object to form.</p> <p>8 THE WITNESS: I think we are in</p> <p>9 a very rich time for investigating the</p> <p>10 role of nongenetic factors for autism.</p> <p>11 I don't think we have specific</p> <p>12 environmental factors with --</p> <p>13 describing that broadly, right. So</p> <p>14 all the things that we talked about</p> <p>15 already: The lifestyle factors and</p> <p>16 the actual agents in the environment</p> <p>17 and the potential other genetic</p> <p>18 factors.</p> <p>19 We don't have strong evidence</p> <p>20 to support a causal association with</p> <p>21 any of those environmental factors</p> <p>22 with perhaps the exception of parental</p> <p>23 age, which, of course, is linked to</p> <p>24 genetics in ways that we can talk</p> <p>25 about, if you want.</p>

<p style="text-align: right;">Page 90</p> <p>1 So I think that we are in an</p> <p>2 exploration phase. We have</p> <p>3 interesting data. We have data that's</p> <p>4 continuing to evolve, but there is</p> <p>5 still a lot of questions.</p> <p>6 MR. SNIDOW: Okay. Can you</p> <p>7 play tab MM?</p> <p>8 (Video played.)</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. All right. And that's what --</p> <p>11 that's what you've tried to do in your work,</p> <p>12 right?</p> <p>13 A. That's right.</p> <p>14 MR. MURDICA: Objection to</p> <p>15 form.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. And I'm not asking about</p> <p>18 conclusively, but do you think that there are</p> <p>19 any environmental factors where it's more</p> <p>20 likely than not that it causes autism?</p> <p>21 MR. MURDICA: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: So, again, I'm</p> <p>24 never going to say that I think an</p> <p>25 environmental factor causes autism.</p>	<p style="text-align: right;">Page 92</p> <p>1 answer that question -- first of all,</p> <p>2 no.</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. Okay.</p> <p>5 A. And to answer that question, we</p> <p>6 need to understand what the definition of an</p> <p>7 epidemic is.</p> <p>8 Q. Right.</p> <p>9 A. And I'm happy to go into that,</p> <p>10 if you'd like.</p> <p>11 Q. Well, I think you think an</p> <p>12 epidemic, you need to know the cause, right?</p> <p>13 A. It's --</p> <p>14 MR. MURDICA: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: An epidemic is</p> <p>17 showing an increase in the actual risk</p> <p>18 of acquiring the disease, not being</p> <p>19 labeled with the disease, but an</p> <p>20 increase in the actual risk of</p> <p>21 acquiring the disease.</p> <p>22 We do not have evidence to</p> <p>23 show -- that would be the incidence,</p> <p>24 right? We do not have evidence to</p> <p>25 show that the incidence of autism</p>
<p style="text-align: right;">Page 91</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Oh, okay.</p> <p>3 A. But I could say that, you know,</p> <p>4 is there evidence in support of a causal</p> <p>5 association. And as I said with parental</p> <p>6 age, I think there is strong and consistent</p> <p>7 evidence from all over the world that the</p> <p>8 older mother and older father both contribute</p> <p>9 to an increased risk of autism.</p> <p>10 Q. But that's it; nothing else?</p> <p>11 MR. MURDICA: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I think there is</p> <p>14 interesting evidence in other areas,</p> <p>15 but nothing that I think is as strong</p> <p>16 as the parental age finding.</p> <p>17 QUESTIONS BY MR. SNIDOW:</p> <p>18 Q. And you wouldn't deem any of</p> <p>19 the other ones causal?</p> <p>20 A. Correct.</p> <p>21 Q. Do you agree it's possible that</p> <p>22 there is currently an epidemic of autism?</p> <p>23 MR. MURDICA: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: So I think to</p>	<p style="text-align: right;">Page 93</p> <p>1 spectrum disorders is increasing, yes,</p> <p>2 and information to show that the</p> <p>3 prevalence is increasing, but those</p> <p>4 are very different things.</p> <p>5 QUESTIONS BY MR. SNIDOW:</p> <p>6 Q. Yeah.</p> <p>7 But do you think you need to</p> <p>8 know the cause of a disease to say whether</p> <p>9 it's an epidemic?</p> <p>10 MR. MURDICA: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: So I think that</p> <p>13 understanding the incidence of disease</p> <p>14 requires knowing what's driving the</p> <p>15 increase in incidences.</p> <p>16 So I believe we cannot</p> <p>17 establish that there's an increased</p> <p>18 incidence in autism spectrum disorder</p> <p>19 because we don't know entirely what</p> <p>20 the causal pathway for autism is.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. But would you agree we don't</p> <p>23 currently know whether there's an autism</p> <p>24 epidemic?</p> <p>25 MR. MURDICA: Objection to</p>

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1 form.

2 THE WITNESS: I would say I

3 believe, based on the data that I've

4 been involved in collecting and

5 publishing, it -- the epidemic is not

6 a function of an increase in

7 incidence; it's a function of a whole

8 host of factors, including increased

9 awareness, change in diagnostic

10 criteria, early age of diagnosis.

11 So I do not count that as an

12 epidemic because it's not an increase

13 in the risk of acquiring the disease.

14 It's an increase in the number of

15 individuals who are labeled with the

16 disease.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Yeah.

19 So you don't think there's an

20 epidemic?

21 A. I do not.

22 MR. SNIDOW: Can we play tab

23 OO?

24 (Video played.)

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Is that you again?

3 A. That's me.

4 MR. MURDICA: Objection to form

5 and to the continued use of these

6 short little video clips from a large

7 video.

8 MR. SNIDOW: Yeah, that's fine.

9 QUESTIONS BY MR. SNIDOW:

10 Q. And there you said we don't

11 know whether there's an epidemic, right?

12 A. So this was in 2014.

13 Q. Yeah.

14 A. And I think that that's what I

15 said in 2014.

16 Q. Okay. Do you agree

17 heritability does not actually tell you what

18 proportion of a trait is determined by the

19 environment?

20 A. Heritability does not determine

21 what proportion of the trait is determined by

22 the environment. Yes, I agree with that.

23 Q. A disease can be heritable and

24 still determined by environmental factors?

25 A. A disease can be heritable, and

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1 environmental factors can still influence the

2 phenotype, yes.

3 Q. So if a her -- we had

4 heritability of -- what do you think autism

5 is, 90 percent?

6 A. 80 to 90 percent.

7 Q. 80?

8 That doesn't mean that autism

9 is 80 percent caused by genetic factors, does

10 it?

11 MR. MURDICA: Objection to

12 form.

13 THE WITNESS: Again, we

14 understand autism to be a genetic

15 disorder. We understand heritability

16 to describe the proportion of the

17 phenotype that is explained by genes.

18 We know that that's not

19 100 percent. We know that there are

20 other factors as we've -- as we've

21 said already that include lifestyle,

22 environment, other genetic factors.

23 (Pinto-Martin Exhibit 603

24 marked for identification.)

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. All right. I'm going to mark a

3 document as Pinto-Martin 603.

4 You see at the top there,

5 National Institutes of Health?

6 A. Barely.

7 Q. Yeah. Not great printing.

8 Do you see the bullet at the

9 bottom that says, "Heritability does not

10 indicate"?

11 A. I do.

12 Q. It says, "Heritability does not

13 indicate what proportion of a trait is

14 determined by genes and what proportion is

15 determined by environment."

16 Did I read that correctly?

17 A. That's what it says.

18 Q. Do you agree?

19 A. I think I just said something

20 similar to that.

21 Q. Okay. It says, "So a

22 heritability of .7 does not mean that a trait

23 is 70 percent caused by genetic factors."

24 Did I read that correctly?

25 A. That's what that says.

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1 Q. Do you agree?

2 A. I agree with that statement.

3 Q. So if someone said that 70 to

4 90 percent of ASD cases are caused by

5 genetics because of the heritability rate

6 that you described, that's inconsistent with

7 this, right?

8 MR. MURDICA: Objection to

9 form.

10 THE WITNESS: I don't know

11 where this came from. I don't know

12 what this is used for. So it's a

13 little hard for me to re -- respond

14 sort of off the cuff on statements

15 like this.

16 QUESTIONS BY MR. SNIDOW:

17 Q. Well, you told me you agreed

18 with that, right?

19 A. So I understand that

20 heritability is not deterministic, but I

21 believe that 80 to 90 percent of autism is

22 described --

23 (Audio interruption.)

24 MR. MURDICA: All right.

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. All right. Ma'am, let's focus

3 on this. You said you agreed with the

4 sentence, "A heritability of .7 does not mean

5 that a trait is 70 percent caused by genetic

6 factors," right?

7 A. Again, this --

8 Q. Wait, sorry. I'm just saying,

9 do -- are you changing your testimony about

10 whether you agree?

11 MR. MURDICA: Objection to

12 form.

13 THE WITNESS: I'm not changing

14 my testimony. I'm trying to

15 contextualize it by saying I don't

16 know where this came from, and I don't

17 know exactly who the audience is. I

18 don't know what it's based on.

19 So it's hard for me to respond

20 to it.

21 QUESTIONS BY MR. SNIDOW:

22 Q. Right.

23 But you said you agreed with

24 the sentence, right?

25 MR. MURDICA: Objection to

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1 form.

2 THE WITNESS: I can agree with

3 something and still have a --

4 QUESTIONS BY MR. SNIDOW:

5 Q. Yeah.

6 A. -- contextualized response, and

7 that's what I'm saying with that.

8 Q. All I'm saying is -- what this

9 is saying is the heritability of -- for

10 autism of 80 to 90 percent does not mean that

11 autism is 80 to 90 percent caused by genetic

12 factors, right?

13 MR. MURDICA: Objection to

14 form.

15 THE WITNESS: I'm not sure I

16 agree with that.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Okay. That's fine.

19 Do you agree that applying

20 Bradford Hill is more like a clinical

21 judgment than experimental science?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: So that's not the

25 way I would describe it because I'm

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1 not a clinician, so I don't apply

2 clinical judgment. I apply

3 epidemiologic judgment.

4 I would agree that it's

5 applying epidemiologic judgment to a

6 body of literature.

7 QUESTIONS BY MR. SNIDOW:

8 Q. When you're doing Bradford

9 Hill, there's no hard-and-fast rules; it is a

10 matter of judgment, right?

11 A. I believe that it's a matter of

12 expert judgment, yes.

13 Q. And when researchers are

14 writing their papers, do you agree they're

15 conservative when assessing causal

16 relationships?

17 MR. MURDICA: Objection to

18 form.

19 THE WITNESS: It's a very broad

20 statement. I can't answer.

21 QUESTIONS BY MR. SNIDOW:

22 Q. All right. PPP.

23 All I am asking is when

24 they're -- when they're publishing, they're

25 reluctant to say causation, aren't they?

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1 MR. MURDICA: Objection to
2 form.
3 THE WITNESS: I can't say that
4 in general. Some people are very
5 willing to say causation. I myself am
6 I think perhaps more conservative than
7 others.
8 (Pinto-Martin Exhibit 605
9 marked for identification.)
10 QUESTIONS BY MR. SNIDOW:
11 Q. All right. I'm going to mark a
12 document as Pinto-Martin 605. This is the
13 Reference Manual on Scientific Evidence.
14 MR. MURDICA: Do you have a
15 copy for me?
16 MR. SNIDOW: I do. I do.
17 QUESTIONS BY MR. SNIDOW:
18 Q. This document, just so you
19 know, is about a thousand pages long, so I've
20 excerpted a couple of chapters.
21 MR. SNIDOW: Jim, this one is
22 widely available, and I think you're
23 familiar with it, too.
24 MR. MURDICA: I am.
25

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1 QUESTIONS BY MR. SNIDOW:
2 Q. So this is the Reference Manual
3 on Scientific Evidence.
4 Do you see that?
5 A. I see that. I don't really
6 know what that -- how it's used or where it's
7 from or any- --
8 Q. Yeah.
9 A. I've never seen it before.
10 Q. All right.
11 A. But, yes, that's what it says.
12 Q. You see it's published by the
13 Federal Judicial Center?
14 A. I see that on the front page.
15 Q. And if you could turn to the
16 page that's marked 62.
17 A. 262? I'm sorry.
18 Q. I'm sorry.
19 A. It's marked 62? I don't see
20 that.
21 Q. 262.
22 A. Marked 262. I don't have a
23 262. I have a 253, a 254.
24 MR. MURDICA: I think he put
25 two parts --

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1 THE WITNESS: I know, but I
2 still don't have a 262.
3 MR. MURDICA: Hold on. Hold
4 on. Hold on. Hold on. Hold on.
5 Hold on.
6 THE WITNESS: It goes from 252
7 to 500 something -- 255.
8 QUESTIONS BY MR. SNIDOW:
9 Q. 599, I'm sorry.
10 A. 590 -- I don't have 599 either.
11 I have 597.
12 Q. Look at that one.
13 MR. MURDICA: I don't have 599
14 either.
15 THE WITNESS: You want to
16 share?
17 Okay. I have page 599. I'm
18 going to get my reading glasses out if
19 you don't mind, because that's pretty
20 small.
21 QUESTIONS BY MR. SNIDOW:
22 Q. Please.
23 A. Okay.
24 Q. And do you see the sentence
25 that begins -- three lines down that begins

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1 "generally"?
2 A. Uh-huh.
3 Q. It says, "Generally researchers
4 are conservative when it comes to assessing
5 causal relationships, often calling for
6 stronger evidence and more research before
7 conclusion of causation is drawn."
8 Do you see that?
9 A. That's what that says.
10 Q. All right. You can put that
11 one aside for now, but hold on to it.
12 Do you agree that it's
13 ultimately a value judgment about whether the
14 evidence is strong enough to warrant a causal
15 inference?
16 MR. MURDICA: Objection to
17 form.
18 THE WITNESS: So I think I
19 would want you to define a value --
20 what did you say, a value --
21 QUESTIONS BY MR. SNIDOW:
22 Q. A value judgment.
23 A. -- judgment?
24 Q. Uh-huh.
25 A. Because I'm not sure exactly

<p style="text-align: right;">Page 106</p> <p>1 what you mean by that. There are -- there</p> <p>2 are a set of criteria, and I try to apply</p> <p>3 those criteria with rigor and consistency,</p> <p>4 and I don't consider that a value judgment.</p> <p>5 I think that's an expert</p> <p>6 opinion judgment.</p> <p>7 Q. Okay. Do you think that</p> <p>8 whether evidence is strong enough to warrant</p> <p>9 the causal inference is open to reasonable</p> <p>10 debate?</p> <p>11 MR. MURDICA: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I think that</p> <p>14 entirely depends on the evidence, so</p> <p>15 reasonable debate is -- it happens in</p> <p>16 science, but I can't in -- sort of out</p> <p>17 of context say "yes" because sometimes</p> <p>18 the answer would be "no."</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Do you think people can</p> <p>21 disagree with one another in good faith about</p> <p>22 whether the evidence is strong enough to</p> <p>23 warrant a causal inference?</p> <p>24 MR. MURDICA: Objection. Form.</p> <p>25 THE WITNESS: Again, I think it</p>	<p style="text-align: right;">Page 108</p> <p>1 four lines down in the corresponding author</p> <p>2 box.</p> <p>3 A. I haven't found me, but I</p> <p>4 believe that I'm in there.</p> <p>5 MR. MURDICA: I saw it. Right</p> <p>6 there.</p> <p>7 THE WITNESS: Okay. Yeah. Got</p> <p>8 it.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. All right. It's defining you</p> <p>11 as member -- as a member of the working group</p> <p>12 in autism risk communication ethics, right?</p> <p>13 A. That's correct.</p> <p>14 Q. And you served on -- in that</p> <p>15 working group?</p> <p>16 A. I did.</p> <p>17 Q. And then it looks like you guys</p> <p>18 published this paper?</p> <p>19 A. Well, I wasn't part of the</p> <p>20 paper itself, but I'm part of the working</p> <p>21 group.</p> <p>22 Q. Do you think you reviewed it</p> <p>23 before it went out?</p> <p>24 A. I don't recall.</p> <p>25 Q. Okay. Let's see if you agree.</p>
<p style="text-align: right;">Page 107</p> <p>1 depends on the body of evidence.</p> <p>2 MR. SNIDOW: Can I have X,</p> <p>3 please?</p> <p>4 (Pinto-Martin Exhibit 606</p> <p>5 marked for identification.)</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. All right. Marking a document</p> <p>8 as Pinto-Martin 606.</p> <p>9 A. Put this aside?</p> <p>10 MR. MURDICA: Uh-huh.</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. All right. Now --</p> <p>13 MR. MURDICA: Can I have my</p> <p>14 copy, please?</p> <p>15 MR. SNIDOW: Yeah.</p> <p>16 MR. MURDICA: Thank you.</p> <p>17 MR. SNIDOW: Yeah.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. All right. This is a</p> <p>20 publication Yudell 2013.</p> <p>21 Do you see that at the top</p> <p>22 there?</p> <p>23 A. I do.</p> <p>24 Q. And if you look down at the</p> <p>25 bottom, you'll see your name. It's about</p>	<p style="text-align: right;">Page 109</p> <p>1 On page 10, at the bottom</p> <p>2 there, do you see a sentence -- sorry, the</p> <p>3 bottom of the second full paragraph, there's</p> <p>4 a sentence that begins "finally"?</p> <p>5 A. Uh-huh.</p> <p>6 Q. It says, "Finally, the notion</p> <p>7 of sufficient or appropriate evidential</p> <p>8 support involves value judgments."</p> <p>9 Did I read that correctly?</p> <p>10 A. That's what that says.</p> <p>11 Q. And that's what this working</p> <p>12 group that you served on said?</p> <p>13 A. Again, I don't know who wrote</p> <p>14 that particular sentence. It looks like it's</p> <p>15 citing to two other references, and that may</p> <p>16 have been their language.</p> <p>17 Q. Uh-huh.</p> <p>18 A. So I don't know who said that.</p> <p>19 Q. Do you agree with it?</p> <p>20 A. As I just said, it depends on</p> <p>21 the definition of value judgment. It's not</p> <p>22 the way I would describe application of the</p> <p>23 Bradford Hill criteria, which was your</p> <p>24 original question.</p> <p>25 Q. Well, this isn't about Bradford</p>

<p style="text-align: right;">Page 110</p> <p>1 Hill, is it?</p> <p>2 A. But that was your original</p> <p>3 question about the --</p> <p>4 Q. No, actually --</p> <p>5 A. -- an actual value judgment.</p> <p>6 Q. No. I actually said whether</p> <p>7 the evidence is enough to warrant a causal</p> <p>8 inference?</p> <p>9 MR. MURDICA: Object -- that's</p> <p>10 not a question.</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Right?</p> <p>13 And so look at it again. It</p> <p>14 says, "Finally, the notion of sufficient or</p> <p>15 appropriate evidential support involves value</p> <p>16 judgments."</p> <p>17 Right?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: That's what it</p> <p>21 says.</p> <p>22 QUESTIONS BY MR. SNIDOW:</p> <p>23 Q. Okay. And if you turn to the</p> <p>24 next page, page 11, at the top of the first</p> <p>25 paragraph, the one that begins with the next</p>	<p style="text-align: right;">Page 112</p> <p>1 MR. MURDICA: Do you want to go</p> <p>2 off the record?</p> <p>3 MR. SNIDOW: Yes, please.</p> <p>4 VIDEOGRAPHER: The time is</p> <p>5 9:59 a.m., and we're off the record.</p> <p>6 (Off the record at 9:59 a.m.)</p> <p>7 VIDEOGRAPHER: The time is</p> <p>8 10:10 a.m., and we're on the record.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Okay. Dr. Pinto-Martin, I'm</p> <p>11 going to go through some associations that</p> <p>12 have been demonstrated in the autism</p> <p>13 literature, and what I want you to do is tell</p> <p>14 me whether you think the most likely</p> <p>15 explanation is chance, bias, confounding or</p> <p>16 causation.</p> <p>17 Okay?</p> <p>18 MR. MURDICA: Object to form.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Ready?</p> <p>21 A. I understand what you're</p> <p>22 proposing to do.</p> <p>23 Q. Okay.</p> <p>24 A. It may be that I'm going to</p> <p>25 want to look at specific studies to inform</p>
<p style="text-align: right;">Page 111</p> <p>1 page, there's a sentence that says,</p> <p>2 "Furthermore"?</p> <p>3 A. I see that sentence.</p> <p>4 Q. It says, "Furthermore, since</p> <p>5 judgements of sufficient evidence are value</p> <p>6 laden, there's no good reason to exclude the</p> <p>7 voices of the broader autism community when</p> <p>8 considering them."</p> <p>9 Right?</p> <p>10 A. That's what that says.</p> <p>11 Q. Do you agree?</p> <p>12 A. I'm not sure exactly what they</p> <p>13 mean there.</p> <p>14 Q. Okay. So you think that even</p> <p>15 though your name is on the front, you didn't</p> <p>16 read this before it went out?</p> <p>17 MR. MURDICA: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I'm not an author</p> <p>20 on this paper. We had multiple</p> <p>21 meetings as a group, and this was a</p> <p>22 publication that was written without</p> <p>23 my involvement. So I am not</p> <p>24 responsible for what's --</p> <p>25 (Audio interruption.)</p>	<p style="text-align: right;">Page 113</p> <p>1 myself about whether one of those is the most</p> <p>2 likely explanation. I'm not sure I can do</p> <p>3 it --</p> <p>4 Q. That's fine.</p> <p>5 A. -- in a vacuum.</p> <p>6 Q. If there's one you aren't sure</p> <p>7 about, you just let me know.</p> <p>8 Okay?</p> <p>9 MR. MURDICA: Object to form.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. All right. Thalidomide?</p> <p>12 A. So thalidomide, to my</p> <p>13 knowledge, there is one study that used data</p> <p>14 and looked retrospectively at whether</p> <p>15 thalidomide increased the risk of autism</p> <p>16 spectrum disorder.</p> <p>17 There are many problems with a</p> <p>18 retrospective design like that. We could</p> <p>19 talk about the problems inherent in recall</p> <p>20 bias and -- so I would say that the jury is</p> <p>21 still out on that one, if you will. One</p> <p>22 study does not establish or disprove the</p> <p>23 hypothesis of a causal association.</p> <p>24 Q. All right. So you don't think</p> <p>25 it's -- the most likely explanation is</p>

<p style="text-align: right;">Page 114</p> <p>1 causation; is that right?</p> <p>2 MR. MURDICA: Object to form.</p> <p>3 THE WITNESS: Again, I'm</p> <p>4 willing to give an opinion when we</p> <p>5 have one study.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. All right. You wouldn't say</p> <p>8 that it's established that thalidomide causes</p> <p>9 autism?</p> <p>10 MR. MURDICA: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: It's -- I would</p> <p>13 say there is very significant</p> <p>14 interesting evidence from one study.</p> <p>15 I would never make an opinion based on</p> <p>16 a single study.</p> <p>17 I think it's interesting. I</p> <p>18 think it's compelling. We will never</p> <p>19 be able to do another study because</p> <p>20 thalidomide is now off the market.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. Yeah.</p> <p>23 A. And, again, with one study and</p> <p>24 the inherent problems, I can't establish that</p> <p>25 something is causal.</p>	<p style="text-align: right;">Page 116</p> <p>1 studies very carefully before I answered a</p> <p>2 question like the one you're addressing.</p> <p>3 Q. All right. Air pollution?</p> <p>4 A. So, again, there is some data</p> <p>5 that suggests that particulate matter in the</p> <p>6 environment, in the air, is associated with</p> <p>7 an increased risk. There are many problems</p> <p>8 with the studies.</p> <p>9 I referred to this earlier in</p> <p>10 the answer to one of your questions because</p> <p>11 air pollution is an ecological exposure. We</p> <p>12 don't have individual level of air pollution</p> <p>13 in a pregnant woman. So I believe that there</p> <p>14 are very interesting data that are very</p> <p>15 challenging to interpret with respect to any</p> <p>16 kind of causal connection.</p> <p>17 Q. Mother's psychiatric</p> <p>18 conditions, do you think that's chance,</p> <p>19 confounding, bias or causation?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: So I think</p> <p>23 maternal psychiatric condition,</p> <p>24 because it is linked to genetics, has</p> <p>25 strong and very consistent evidence</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Okay. But what do you think</p> <p>2 the most likely explanation is? Is it</p> <p>3 chance, confounding, bias or causation?</p> <p>4 MR. MURDICA: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: I would want to</p> <p>7 look at the study, look at the sample</p> <p>8 size, look at the exposure, look at</p> <p>9 the assessment of outcome.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. All right. That's fine.</p> <p>12 Misoprostol?</p> <p>13 A. So that's an abortifacient.</p> <p>14 And so women who wanted to end their</p> <p>15 pregnancy took that medication. And then</p> <p>16 those who didn't lose their baby were then</p> <p>17 followed and autism was assessed in those</p> <p>18 babies.</p> <p>19 Again, I think that there's</p> <p>20 interesting evidence to suggest that there</p> <p>21 may be an association with an increased risk</p> <p>22 of autism among those women, but it's a very</p> <p>23 complicated study to assess, given the</p> <p>24 selection bias going into a study like that,</p> <p>25 and I would want to review the study -- the</p>	<p style="text-align: right;">Page 117</p> <p>1 with respect to both ASD and ADHD.</p> <p>2 We don't understand the causal</p> <p>3 pathway from maternal genetics through</p> <p>4 psychiatric history of the mother to</p> <p>5 increased risk of autism in the</p> <p>6 offspring because we don't know how</p> <p>7 the genes operate.</p> <p>8 So, again, I think the evidence</p> <p>9 there is very strong and consistent</p> <p>10 and compelling. If you -- if you</p> <p>11 wanted me to review that body of</p> <p>12 literature and give you my best</p> <p>13 estimate, I'd be happy to do that,</p> <p>14 but --</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. But sitting here right now, can</p> <p>17 you tell me that mother's psychiatric</p> <p>18 conditions causes autism? Can you tell me</p> <p>19 that?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: So, again, as I</p> <p>23 mentioned before, based on</p> <p>24 observational studies, I will never</p> <p>25 say that something causes autism.</p>

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Okay.

3 A. I would say that the strength

4 of the evidence on psychiatric history is

5 substantial, and that it looks to be a risk

6 factor that elevates the outcome of autism in

7 offspring.

8 Q. Okay. Valproic acid?

9 A. Again, very interesting data.

10 We know a lot about valproic acid because

11 it's a prescription medication, so we know

12 very specific information about the timing

13 and the dose and the duration of valproic

14 acid with respect to a mother's pregnancy.

15 We also know the indication for

16 use because it's given for very specific

17 reasons: Seizure disorder, migraine. So the

18 evidence is, again, interesting and

19 compelling and I think strong in many cases,

20 and we are still continuing to evaluate it.

21 Q. Do you think that the evidence

22 for valproic acid right now is strong enough

23 to say it's most likely causal?

24 MR. MURDICA: Objection to

25 form.

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1 THE WITNESS: I would want to

2 review the valproic acid studies. I

3 haven't done that in a while, and I

4 think they are still ongoing. I think

5 people are still producing evidence,

6 but I think that, again, the data is

7 interesting, compelling, worthy of

8 further consideration, could well be

9 confounded by genetics.

10 There could be other

11 explanations for it, so I'm unwilling

12 to say that anything is causal without

13 a thorough evaluation of that

14 literature.

15 QUESTIONS BY MR. SNIDOW:

16 Q. Well, you've got two sections

17 on valproic acid in your report, right?

18 A. I believe that's true, both in

19 the autism and ADHD section.

20 Q. And you reviewed the literature

21 before writing those sections, I assume.

22 A. The literature that existed to

23 date, yeah.

24 Q. Okay. So can you tell me, does

25 that literature make the most likely

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1 explanation for the valproic acid association

2 causation?

3 A. Again, from an observational

4 study, I cannot establish causation. I would

5 say that the evidence on valproic acid is

6 suggestive of an increased risk of autism

7 spectrum disorder among women who took it.

8 That doesn't necessarily establish causality.

9 Q. I agree.

10 A. Okay.

11 Q. But you say in your report you

12 don't think that the evidence for Tylenol is

13 enough to establish causation, right?

14 MR. MURDICA: Object --

15 objection to form.

16 THE WITNESS: That's correct.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Okay. And I assume that

19 there's some level of evidence where you

20 would have a different opinion, right?

21 A. So as I said, the things that I

22 think about when I'm trying to evaluate

23 whether there is evidence in support of a

24 causal association -- not cause, but a causal

25 association -- I look at the information on

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1 the exposure, what is the precision with

2 respect to timing, dose, duration; what is

3 the precision with respect to assessment of

4 outcome.

5 And in the acetaminophen

6 literature, we have problems in both of those

7 domains, and so it renders my opinion --

8 supports my opinion, which is that there is

9 not evidence of a causal association.

10 Q. Right.

11 I was asking about valproic

12 acid, right? And does the literature for

13 valproic acid support the statement that the

14 most likely explanation is causation?

15 Does it or no?

16 MR. MURDICA: Objection to

17 form.

18 QUESTIONS BY MR. SNIDOW:

19 Q. Let me ask it a different way.

20 If we had had a report saying,

21 "We think valproic acid causes autism," and

22 you were writing a report like yours now,

23 would you write, "I do or I don't think that

24 the evidence for valproic acid supports a

25 causal association"?

<p style="text-align: right;">Page 122</p> <p>1 MR. MURDICA: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: So I tried to</p> <p>4 answer this question a couple of</p> <p>5 times.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. Right.</p> <p>8 But can you answer it?</p> <p>9 A. I'll try again.</p> <p>10 Q. Okay. Would you write that</p> <p>11 sentence? Would you write, "I think the</p> <p>12 evidence for valproic acid does support a</p> <p>13 causal association," or would you write, "I</p> <p>14 think the evidence for valproic acid does not</p> <p>15 report a causal association"?</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. Can you answer that question?</p> <p>20 If you can't answer it, we'll</p> <p>21 move on. But can you answer that?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I believe in my</p> <p>25 report I agree that the evidence</p>	<p style="text-align: right;">Page 124</p> <p>1 through them one at a time, and I</p> <p>2 think I answered them one at a time.</p> <p>3 I can't answer them as a group because</p> <p>4 I differ in the -- with respect to the</p> <p>5 individual agent, and we talked about</p> <p>6 it.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Right.</p> <p>9 But are there any of them where</p> <p>10 you'd say, "I think causation is the most</p> <p>11 likely, it's just not definitive"?</p> <p>12 A. No.</p> <p>13 Q. No. Okay.</p> <p>14 Same question for fever: Do</p> <p>15 you think causation is the most likely, even</p> <p>16 if not definitive, or do you think not enough</p> <p>17 evidence?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I think fever is</p> <p>21 a very interesting finding that we've</p> <p>22 seen replicated over and over again,</p> <p>23 and we also have some evidence to</p> <p>24 suggest that it might be confounded by</p> <p>25 genetics.</p>
<p style="text-align: right;">Page 123</p> <p>1 supports a causal link. That doesn't</p> <p>2 mean it establishes it --</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. That's fine.</p> <p>5 A. -- but it supports it.</p> <p>6 Q. That's all I wanted.</p> <p>7 The most likely explanation is</p> <p>8 causation, it's not just certain.</p> <p>9 Is that right?</p> <p>10 MR. MURDICA: Object to form.</p> <p>11 THE WITNESS: I'll agree with</p> <p>12 that statement.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. Okay. And maybe I should have</p> <p>15 clarified this before, but any of these other</p> <p>16 risk factors we talked about, would you give</p> <p>17 the same answer that you did for valproic</p> <p>18 acid?</p> <p>19 Like, would you say</p> <p>20 thalidomide, misoprostol, air pollution,</p> <p>21 mother's psychiatric conditions, not</p> <p>22 definitive, but would you say the most likely</p> <p>23 explanation is causation?</p> <p>24 MR. MURDICA: Object to form.</p> <p>25 THE WITNESS: We just went</p>	<p style="text-align: right;">Page 125</p> <p>1 So, again, you cannot cause --</p> <p>2 say that something is causally</p> <p>3 associated if there's a clear -- a</p> <p>4 confounder, and that's true across the</p> <p>5 board.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. So not enough evidence for</p> <p>8 fever; is that right?</p> <p>9 A. Again, I don't want to be black</p> <p>10 and white like that. The evidence on fever</p> <p>11 is very compelling. But if fever is a marker</p> <p>12 for something else, right, for some</p> <p>13 underlying immune disorder or some genetic</p> <p>14 factor in the mother, fever itself is not the</p> <p>15 causal agent, if you will.</p> <p>16 So I have to -- I have to</p> <p>17 always contextualize like that.</p> <p>18 Q. But if I said, "I think fever</p> <p>19 does cause autism," I read a report, and you</p> <p>20 were writing your report, and you had to</p> <p>21 write the sentence, "I think there's enough</p> <p>22 evidence about fever to say it is causal," or</p> <p>23 the sentence, "I think there isn't enough</p> <p>24 evidence to say it's causal," which one of</p> <p>25 those would you pick?</p>

<p style="text-align: right;">Page 126</p> <p>1 MR. MURDICA: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: So I find it</p> <p>4 frustrating that you're asking me to</p> <p>5 come down, you know, on a black -- in</p> <p>6 a black and white way.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. You came down on one side in</p> <p>9 this report, right? You said there's not</p> <p>10 enough evidence on acetaminophen, didn't you?</p> <p>11 MR. MURDICA: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I did.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Okay. Is there enough evidence</p> <p>16 for fever?</p> <p>17 MR. MURDICA: I need to make my</p> <p>18 objections.</p> <p>19 Object to form.</p> <p>20 And you need to ask questions.</p> <p>21 Not, like, dialogue.</p> <p>22 MR. SNIDOW: That's fine.</p> <p>23 QUESTIONS BY MR. SNIDOW:</p> <p>24 Q. Do you think there's enough</p> <p>25 evidence for fever or no?</p>	<p style="text-align: right;">Page 128</p> <p>1 there may be confounding, and it may</p> <p>2 represent some other factor</p> <p>3 unmeasured.</p> <p>4 MR. SNIDOW: All right. Can I</p> <p>5 play tab RR, Michael?</p> <p>6 MICHAEL KAUFFMANN: Yeah.</p> <p>7 MR. SNIDOW: Thank you.</p> <p>8 (Video played.)</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Is that your voice on there?</p> <p>11 A. That is my voice.</p> <p>12 Can you tell me when this</p> <p>13 was --</p> <p>14 Q. I believe that one's either</p> <p>15 July 2011 or January 2012. Both dates are on</p> <p>16 there.</p> <p>17 A. It was a very long time ago.</p> <p>18 Q. Well, right.</p> <p>19 But in the interim, the</p> <p>20 evidence on valproic acid has become</p> <p>21 stronger, right?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: So I just want to</p> <p>25 point out that the things that you're</p>
<p style="text-align: right;">Page 127</p> <p>1 A. I think the evidence on fever</p> <p>2 is compelling and interesting, and we don't</p> <p>3 understand the causal pathway --</p> <p>4 Q. Okay.</p> <p>5 A. -- that would lead from a fever</p> <p>6 in the mother to an increased risk of autism</p> <p>7 in the child. And so we need to keep</p> <p>8 studying it and keep working on it, which is</p> <p>9 what we're doing.</p> <p>10 Q. Smoking?</p> <p>11 A. The evidence on smoking is --</p> <p>12 are we talking about any outcome, or can you</p> <p>13 be specific about --</p> <p>14 Q. Autism, ASD. If you had to</p> <p>15 write the sentence, "I think there's</p> <p>16 sufficient evidence for smoking," or "I think</p> <p>17 there's not sufficient evidence for smoking,"</p> <p>18 which one would you write?</p> <p>19 MR. MURDICA: Object to form.</p> <p>20 THE WITNESS: I would --</p> <p>21 similar to some of the prior</p> <p>22 responses, I would say there is</p> <p>23 interesting evidence. My review of</p> <p>24 the literature does not suggest that</p> <p>25 that's a causal association but that</p>	<p style="text-align: right;">Page 129</p> <p>1 pulling up that reflect my opinions</p> <p>2 are from many years ago, and my</p> <p>3 thinking about the etiology of autism</p> <p>4 spectrum disorder and ADHD and other</p> <p>5 neurodevelopmental disorders has</p> <p>6 evolved along with the science. So I</p> <p>7 think that that's what I believed</p> <p>8 then, and perhaps my opinion would</p> <p>9 change over time.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. Okay. Do you think that SSRIs</p> <p>12 cause autism?</p> <p>13 A. I do not.</p> <p>14 Q. All right. So you think not</p> <p>15 enough evidence on SSRIs, right?</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: So, actually,</p> <p>19 there's a lot of evidence on SSRIs.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. No, no, sorry. Not enough</p> <p>22 evidence to say causation, right?</p> <p>23 A. Again --</p> <p>24 MR. MURDICA: Objection.</p> <p>25 THE WITNESS: This is -- this</p>

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1 is the problem that I have here.
 2 You're asking me to opine on an
 3 exposure which we have since learned,
 4 including data from our own research,
 5 is confounded by psychiatric history
 6 of the mother.
 7 So it is a marker for an
 8 increased risk but in and of itself
 9 does not cause an increased risk. So
 10 I can't just say yes or no.
 11 It has been demonstrated that
 12 there's an increased association with
 13 SSRI, but that is not a causal
 14 association because it was confounded
 15 by the underlying maternal psychiatric
 16 history.
 17 Once you control for that, the
 18 association diminishes to the null.
 19 QUESTIONS BY MR. SNIDOW:
 20 Q. That's what I'm trying to get.
 21 For SSRIs you think the most likely
 22 explanation is confounding; is that right?
 23 MR. MURDICA: Objection to
 24 form.
 25 THE WITNESS: I know it's

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1 confounding.
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. You know it's confounding.
 4 Okay.
 5 For thalidomide, here you
 6 present it as an environmental risk factor,
 7 right?
 8 MR. MURDICA: Object --
 9 objection to form.
 10 THE WITNESS: In 2011, that's
 11 how I presented it.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Has there been another study on
 14 thalidomide since then?
 15 A. No. And as I said, we will
 16 never have another study. We had one study.
 17 So in 2011 I was willing to characterize it
 18 that way.
 19 Q. Yeah.
 20 A. I think I'm a little more
 21 careful now because one study does not
 22 establish that something is causal.
 23 Q. I'm sorry. I just want on the
 24 record: There hasn't been a thalidomide
 25 study between 2011 and now, has there?

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1 A. Not to my knowledge.
 2 Q. All right.
 3 A. I haven't searched the
 4 literature, but I can't imagine how one --
 5 someone would do one.
 6 Q. I couldn't either. That's why
 7 I was asking.
 8 Do you think any of the ones we
 9 went through - the thalidomide, misoprostol,
 10 fever, valproic acid, smoking - do you think
 11 there are ones that are -- where there's room
 12 for disagreement among epidemiologists about
 13 whether they're causal or not?
 14 MR. MURDICA: Objection to the
 15 form.
 16 THE WITNESS: So you asked me
 17 about a whole host of questions. I
 18 think you need to go through them one
 19 at a time.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. Okay. That's fine.
 22 A. And we could really then
 23 determine.
 24 Q. Do you think there's room for
 25 disagreement on whether thalidomide is

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1 causal?
 2 A. I think there's room for
 3 disagreement on whether someone would
 4 characterize it as causal --
 5 Q. Okay.
 6 A. -- based on a single study.
 7 Q. Great.
 8 Misoprostol, do you think
 9 there's room for disagreement on whether
 10 misoprostol is causal?
 11 MR. MURDICA: Objection to
 12 form.
 13 THE WITNESS: Again, it's --
 14 it depends on how you define causal,
 15 right, and how you interpret that
 16 statement. Personally, I would not be
 17 willing to assign causality on the
 18 basis of observational studies.
 19 Other epidemiologists may be
 20 more willing to do that, so we may
 21 have different opinions based on our
 22 willingness to assign causality on the
 23 basis of observational data.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. And nothing wrong with that,

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1 right? It's just disagreements --

2 A. It's the way it works.

3 MR. MURDICA: Objection to

4 form.

5 QUESTIONS BY MR. SNIDOW:

6 Q. It's the way it works in

7 science generally, right?

8 MR. MURDICA: Objection to

9 form.

10 THE WITNESS: It's a broad

11 statement. It's the way it works in

12 my world of epidemiology -- perinatal

13 epidemiology.

14 QUESTIONS BY MR. SNIDOW:

15 Q. That's right.

16 For fever, do you think there's

17 room for disagreement about whether it's

18 causal?

19 A. So I would say for fever, it's

20 not really about disagreement as much as

21 nuanced understanding of what fever

22 represents and a sense of we need to know

23 more. You know, is it confounded by

24 genetics? Is it -- is it immune dysfunction?

25 I think fever has interesting

Page 135

1 data that deserves further exploration.

2 Q. But let me ask it this way. If

3 someone said, I think fever does cause

4 autism, do you think that's a reasonable

5 position or no?

6 MR. MURDICA: Objection to

7 form.

8 THE WITNESS: I think it

9 depends on the person and the context

10 in which they're saying that.

11 QUESTIONS BY MR. SNIDOW:

12 Q. If an epidemiologist, one of

13 your colleagues, came to you and said, hey, I

14 actually think fever is causal, I know you

15 disagree, do you think that's a reasonable

16 thing for them to say or not?

17 A. I think it's perhaps a naïve

18 thing because it's a not a very nuanced

19 understanding of how fever might relate to an

20 increased risk of autism.

21 Q. Okay.

22 A. Is it wrong? It depends on how

23 you define "causal."

24 Q. For ADHD, besides genetics, are

25 there any risk factors that you think there

Page 136

1 is enough evidence to say, this is causal?

2 MR. MURDICA: Objection to

3 form.

4 THE WITNESS: Not to my

5 knowledge. I think there's some ones

6 that are interesting markers, but not

7 in and of themselves supportive of a

8 causal link.

9 QUESTIONS BY MR. SNIDOW:

10 Q. How about valproic acid?

11 MR. MURDICA: Objection to

12 form.

13 THE WITNESS: We've talked

14 about valproic acid. I think there

15 is, you know, interesting and

16 compelling data that we need to

17 continue to evaluate.

18 QUESTIONS BY MR. SNIDOW:

19 Q. Do you think the most likely

20 explanation for the valproic acid association

21 with ADHD is causation?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: I don't know that

25 I can answer that yet. I think I

Page 137

1 would want to see more studies before

2 I was able to really --

3 QUESTIONS BY MR. SNIDOW:

4 Q. Well, you have a section of

5 your report on valproic acid and ADHD, right?

6 A. Uh-huh.

7 Q. Is that right?

8 A. I do.

9 Q. So you read those studies?

10 A. I did.

11 Q. All right. And based on those

12 studies that you read, do you think that

13 there's enough evidence to say that valproic

14 acid causes ADHD?

15 MR. MURDICA: Objection to

16 form.

17 THE WITNESS: So, again, I

18 would never say an individual agent

19 causes ASD or ADHD.

20 QUESTIONS BY MR. SNIDOW:

21 Q. Oh, never?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: I would not say

25 on the basis of the data on valproic

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1 acid that there is a causal
2 association because it's observational
3 data, and we have to always take into
4 account the potential for bias, the
5 potential for genetic confounding, the
6 potential for confounding by
7 indication, all of the things that
8 we've talked about.

9 QUESTIONS BY MR. SNIDOW:

10 Q. Okay. You think that
11 scientists should keep studying the
12 association between prenatal APAP exposure
13 and ADHD?

14 A. So I imagine that there are
15 people that have data that might be relevant
16 to the question at hand. I would never say,
17 don't analyze data that exists that might
18 help to resolve what appears to be an ongoing
19 debate about whether there is any causal
20 association.

21 And the value of additional
22 publications and data, in my mind, would be
23 the public health value, the benefit to
24 pregnant women who experience pain or
25 difficulty sleeping or whatever the case may

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1 be for whom APAP is an effective and safe
2 medication.

3 And so it would be very nice
4 for women not to have to worry about that
5 during pregnancy.

6 Q. Yeah.

7 A. That would be the value of
8 additional studies, in my mind.

9 Q. You mentioned the ongoing
10 debate about whether it's causal or not.

11 Do you know any of the
12 epidemiologists on the other side of that
13 debate that think it is causal?

14 A. Not personally.

15 Q. Okay. Do you have any reason
16 to think that the people on the other side of
17 the debate, about whether it's causal or not,
18 are bad epidemiologists?

19 MR. MURDICA: Objection to
20 form.

21 THE WITNESS: Again, if you
22 asked me about a specific person, I --
23 you know, I don't know everyone's
24 record. I don't know enough about
25 those individuals to opine about their

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1 integrity or their career.

2 QUESTIONS BY MR. SNIDOW:

3 Q. Sure.

4 When you -- when you saw their
5 names, did any of them jump out to you and
6 say, oh, that's a -- he's a known quack
7 who works in this field?

8 MR. MURDICA: Objection to
9 form.

10 THE WITNESS: I don't typically
11 think of people as quacks or
12 non-quacks.

13 QUESTIONS BY MR. SNIDOW:

14 Q. Yeah.

15 A. And so I look at their career,
16 and I can make a judgment based on that, but
17 I don't have any specific response to the
18 individuals who are involved in this
19 litigation.

20 Q. In this debate. I meant in the
21 broader literature.

22 MR. MURDICA: Objection to the
23 form.

24 THE WITNESS: Again, I don't
25 have an opinion.

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1 QUESTIONS BY MR. SNIDOW:

2 Q. When you saw the names of the
3 epidemiologists on the other side of the
4 debate about whether acetaminophen causes
5 autism, did you -- did you see any of them
6 and say, ah, I've actually noticed they
7 published bad studies in the past?

8 MR. MURDICA: Objection to the
9 form.

10 THE WITNESS: I didn't evaluate
11 them with that eye, but it didn't --
12 it didn't strike me that way.

13 QUESTIONS BY MR. SNIDOW:

14 Q. Okay. Do you think as of now
15 we can say with certainty that there's no
16 causal relationship between prenatal APAP
17 exposure and ASD?

18 A. I do.

19 Q. You can say it with certainty?

20 A. I think that based on the body
21 of evidence that exists today, there is no
22 peer-reviewed, published epidemiologic
23 evidence to support a causal association
24 between acetaminophen and ADHD or A -- or ASD
25 in the offspring.

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1 Q. That's a little different. I'm
2 not actually asking about the body of
3 literature.
4 I'm saying, are you certain
5 that there is no causal relationship between
6 prenatal APAP exposure and ASD?
7 A. I understand that that's what
8 you're asking me.
9 Q. Okay.
10 A. My only way to evaluate and
11 answer that question is based on the existing
12 body of literature. I'm an epidemiologist.
13 That's what I was asked to do in this
14 litigation, and that's what I've done. And
15 that's what my opinion is based on.
16 Q. Right.
17 But I'm saying -- let me ask it
18 a different way.
19 Did any of the papers that you
20 reviewed have the conclusion, based on our
21 study, we now know for sure that APAP does
22 not cause ASD? Any of them say that?
23 MR. MURDICA: Objection to the
24 form.
25 THE WITNESS: I don't think

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1 that any epidemiologist would make a
2 conclusion like that based on a single
3 study, which is what they've authored.
4 QUESTIONS BY MR. SNIDOW:
5 Q. Well, how about the ones who
6 did like meta-analysis or literature reviews,
7 you read those too, right?
8 A. I did read those.
9 Q. And did any of them say, I've
10 read the literature and I can say with
11 100 percent certainty that prenatal APAP
12 exposure doesn't cause autism?
13 A. Again, I don't believe a
14 credible epidemiologist would ever state an
15 opinion like that.
16 I will tell you what the
17 meta-analyses' authors did say which is, we
18 can't determine because there is so many
19 potential confounders and biases in this
20 literature.
21 Q. Okay. Did any of the papers
22 you reviewed say, based on the data in this
23 study, we're sure that this association is
24 entirely spurious?
25 A. Again, I don't think a credible

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1 epidemiologist would ever make a statement
2 like that in a paper. When you are writing a
3 manuscript, you're using the body of data
4 that you have for that paper, for that
5 analysis. It's a single analysis or a set of
6 analyses, and we don't determine yes or no.
7 Epidemiology is an iterative
8 science, as I've said in my report, and we
9 build evidence over time, and that is why we
10 need to use a set of criteria to evaluate
11 that body of evidence at the end.
12 Q. Did any of the papers that you
13 reviewed state an opinion that there is no
14 risk to the developing fetus from prenatal
15 APAP exposure? Any of them say that?
16 A. I would have to review the
17 articles to see if that was a statement that
18 any of them made. I -- I can't just recall
19 that off the top of my head.
20 Q. None of them come to mind,
21 though, right?
22 MR. MURDICA: Objection to
23 form.
24 THE WITNESS: Again, I would
25 want to review the studies and

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1 evaluate the statements they made in
2 the context of their assessment of
3 their data and their discussion of
4 that data and the limitations of that
5 data and the interpretation of that
6 data.
7 QUESTIONS BY MR. SNIDOW:
8 Q. Yeah.
9 Any studies in the literature
10 say that the consistency factor of Bradford
11 Hill is not satisfied when looking at the
12 overall literature?
13 A. Again, I --
14 MR. MURDICA: Objection to
15 form.
16 THE WITNESS: I -- so that
17 would be a meta-analysis I would -- I
18 would imagine. You wouldn't do that
19 in an individual study because we
20 apply Bradford Hill to a set of
21 studies.
22 And again, I don't recall from
23 the meta-analyses what the specific
24 findings with respect to the Bradford
25 Hill criteria were, but I'd be happy

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1 to look through them, if you want me
2 to.

3 QUESTIONS BY MR. SNIDOW:
4 Q. No, that's fine. If you don't
5 remember.

6 And the same question for any
7 of the other Bradford Hill criteria, did any
8 of the studies they reviewed say, this factor
9 of Bradford Hill is not satisfied for this
10 literature?

11 MR. MURDICA: Objection. Form.
12 THE WITNESS: I would review
13 the meta-analyses for those specific
14 statements. I don't recall offhand
15 whether any of them were willing to
16 say that, but -- able to say that.

17 QUESTIONS BY MR. SNIDOW:
18 Q. I assume you think that the
19 APAP label should not warn about the risk of
20 autism or ADHD?

21 MR. MURDICA: Objection to the
22 form.

23 THE WITNESS: I have no opinion
24 about the label. That's not what I
25 was asked to review, and I have never

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1 seen it.

2 I mean, maybe I've seen it, but
3 it's not something that I reviewed as
4 part of this engagement.

5 QUESTIONS BY MR. SNIDOW:
6 Q. Well, do you think it would be
7 a truthful statement to put on the label that
8 some studies have shown that prenatal APAP
9 exposure causes autism?

10 MR. MURDICA: Objection to
11 form.

12 QUESTIONS BY MR. SNIDOW:
13 Q. I'm sorry, is associated with
14 autism?

15 MR. MURDICA: Objection to the
16 form.

17 THE WITNESS: Again, that's not
18 my area of expertise. I was not asked
19 to opine on the label, and I don't
20 have an opinion based on my expert
21 evaluation of the literature.

22 QUESTIONS BY MR. SNIDOW:
23 Q. Would that be a true statement,
24 though, some studies have shown that prenatal
25 APAP exposure increases the risk of autism?

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1 MR. MURDICA: Same objection.
2 THE WITNESS: Again, we're
3 talking about the label, and it's not
4 something that I'm willing to opine
5 on.

6 QUESTIONS BY MR. SNIDOW:
7 Q. Put the label aside.
8 If I said some studies have
9 shown an association between prenatal APAP
10 exposure and autism, is that true or false?

11 MR. MURDICA: Objection to the
12 form.

13 THE WITNESS: So that's a very
14 general statement that comes out of
15 nowhere, and I don't know who the
16 audience is. I don't know what
17 studies you're considering. I can't
18 agree or disagree to a statement like
19 that.

20 QUESTIONS BY MR. SNIDOW:
21 Q. You can't agree or disagree
22 whether some studies have shown an
23 association between prenatal APAP exposure
24 and autism?

25 MR. MURDICA: Objection to the

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1 form.

2 THE WITNESS: I would want to
3 know what the "some studies" are.

4 QUESTIONS BY MR. SNIDOW:
5 Q. I know, but that's all I'm
6 saying. They exist, don't they?

7 MR. MURDICA: Objection to
8 form.

9 THE WITNESS: Again, I would
10 want to be specific in my response.
11 I'm not willing to make a general
12 statement like that.

13 MR. SNIDOW: Can I have the
14 ELMO, please?

15 Jim, you can have an objection
16 to my demonstrative.
17 Okay?

18 QUESTIONS BY MR. SNIDOW:
19 Q. I pulled this from page 17 of
20 your report.
21 Look familiar?
22 And I'll tell you what I did to
23 it in a second. But do you see on page 17 --
24 A. It looks a little different
25 than what I'm -- yeah.

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1 Q. So you've made it general.
 2 I've just made it specific to this case.
 3 But you agree this is -- this
 4 accurately describes what you're suggesting
 5 when you're talking about confounding?
 6 A. Yes.
 7 Q. Okay. And I made one for
 8 autism, and I made one for ADHD.
 9 A. Okay.
 10 Q. Okay. And you think that this
 11 is what's going on here. You think there's a
 12 confounder that's associated with prenatal
 13 APAP use and autism?
 14 A. Correct.
 15 MR. MURDICA: Objection to
 16 form.
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. Now, for this to be a
 19 confounder, you agree the confounder has to
 20 cause autism, right?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: The confounder
 24 has to be associated with autism.
 25

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. All right. We'll get to
 3 that to -- in a second. But for now,
 4 confounder has to be associated with autism,
 5 right?
 6 A. Uh-huh.
 7 Q. And the confounder has to be
 8 associated with prenatal APAP use.
 9 A. That's the definition of a
 10 confounding variable.
 11 Q. All right. So for this
 12 association, tell me, what should I write
 13 here for confounding variables? I know
 14 genetics is one of them, right?
 15 MR. MURDICA: Objection to
 16 form.
 17 THE WITNESS: Genetics.
 18 QUESTIONS BY MR. SNIDOW:
 19 Q. All right. Any other ones?
 20 A. Indication for use.
 21 Q. Okay. Uh-huh.
 22 Any other ones?
 23 A. I'm going to leave it at that
 24 for confounding variable.
 25 Q. Okay. And for ADHD, should I

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1 write genetics again?
 2 A. You should.
 3 Q. And indication?
 4 A. Uh-huh.
 5 Q. And indication is whether the
 6 mother's using it for fever or pain and so
 7 on?
 8 A. It's the indication for the use
 9 of acetaminophen, correct.
 10 Q. All right. So for autism, what
 11 evidence -- what paper suggests that the
 12 genes of the mother that cause autism or
 13 associated with autism are associated with
 14 prenatal APAP use?
 15 MR. MURDICA: Objection to the
 16 form.
 17 THE WITNESS: So because we
 18 don't understand all of the genetic
 19 contribution, the specific genes that
 20 cause autism, no one has been able to
 21 directly study that.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Okay. All right. That's fine.
 24 So --
 25 MR. MURDICA: She was going to

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1 continue answering, and you
 2 interrupted her. Please don't do
 3 that.
 4 THE WITNESS: So because we
 5 don't know the specifics of the genes
 6 that cause autism and we, therefore,
 7 can't test for them to see if they are
 8 a specific confounder, what we have
 9 done is used statistical techniques to
 10 assess whether genes might play a
 11 role.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Right.
 14 What paper is that?
 15 A. In the -- in the autism
 16 literature, there is not a study that has
 17 done what I would consider the best control
 18 for genetics, which would be a sibling
 19 control, and so we don't have sufficient
 20 evidence to really support that as a -- as a
 21 confounding variable and yet, because of what
 22 we know about autism and its genetic
 23 components, we can be sure that it is a
 24 potential confounder.
 25 And, you know, we talk about

Page 154

1 potential confounder, and then we test to see
 2 if it's there.
 3 Q. All right. So you said we
 4 don't have sufficient evidence.
 5 Okay?
 6 MR. MURDICA: I don't hear a
 7 question.
 8 MR. SNIDOW: No, no, no. Nope.
 9 You can have the objection.
 10 MR. MURDICA: Well, there is no
 11 question.
 12 MR. SNIDOW: I'm going to turn
 13 to the next one.
 14 That's fine. I'll ask one.
 15 So here's one --
 16 MR. MURDICA: You can't just
 17 write stuff down that she didn't say.
 18 MR. SNIDOW: She absolutely
 19 said it.
 20 MR. MURDICA: You can't take it
 21 out of context.
 22 MR. SNIDOW: There's a
 23 transcript. There's a transcript.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. This is the one for ADHD.

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1 So you agree for it to be a
 2 confounder, the confounder has to be
 3 associated with prenatal APAP use, right?
 4 A. Correct.
 5 Q. What evidence is there that
 6 genetics that determine ADHD are associated
 7 with prenatal APAP use?
 8 A. So we have studies that have
 9 evaluated both the polygenic risk score and
 10 maternal psychiatric issues and their
 11 propensity to ingest acetaminophen during
 12 pregnancy.
 13 And they support the
 14 association that the women who have that
 15 propensity for autism, whether it be through
 16 PRS or through report of their own
 17 psychiatric history --
 18 Q. Yeah.
 19 A. -- are more likely to use APAP
 20 during pregnancy than women who do not.
 21 Q. And that study is called
 22 Leppart, right?
 23 A. Right.
 24 Q. So I'm going to write Leppart
 25 here, and that's 2019, right?

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1 A. Uh-huh.
 2 Q. And that was a PRS study,
 3 right?
 4 A. Correct.
 5 Q. And it looked at a polygenic
 6 risk score, which ones were associated with
 7 ADHD, and then looked at whether it was
 8 associated with acetaminophen, right?
 9 A. Uh-huh.
 10 Q. Okay. What did the Leppart
 11 study show for autism?
 12 A. So the Leppart study for
 13 autism, I would want to review specifically.
 14 Q. Okay. Yeah. That's fine.
 15 A. So I am sure to state the
 16 correct numbers. Okay?
 17 MR. MURDICA: Are you providing
 18 it to her? Is that what you're doing?
 19 MR. SNIDOW: No, she's showing
 20 me. She's got it.
 21 THE WITNESS: I'm sorry?
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Are you looking at your report?
 24 What are you looking at?
 25 A. I was going to look at my

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1 report, but I can also look at the study
 2 itself, and that's probably what I'll do.
 3 Q. Yeah. All right.
 4 A. I just want to make sure I cite
 5 the numbers correctly.
 6 (Pinto-Martin Exhibit 607
 7 marked for identification.)
 8 QUESTIONS BY MR. SNIDOW:
 9 Q. So this will be 607, which is
 10 tab JJ for me.
 11 MR. SNIDOW: There you go. Are
 12 you going to want this?
 13 MR. MURDICA: Yes. Thank you.
 14 QUESTIONS BY MR. SNIDOW:
 15 Q. All right. And if you turn to
 16 838.
 17 Do you see that?
 18 A. Uh-huh.
 19 Q. No association, right, for
 20 autism?
 21 A. So we're looking at Table 3?
 22 Q. Uh-huh. No, 2.
 23 A. Okay. We're looking at
 24 Table 2. ASD, PRS and acetaminophen. They
 25 report -- they do not report a statistically

Page 158

1 significant association, that's correct.

2 Q. Almost -- I mean, almost

3 exactly null, right?

4 A. I would say the first one is --

5 yeah, is null and the second one is very

6 close to null.

7 Q. Okay. So I'm going to write

8 Leppart, no association.

9 A. And I would like to point out

10 that a polygenic risk score does not capture

11 the entire universe of genetic risk because

12 we, as I said before, don't understand all of

13 the genes that cause or interact to cause

14 autism.

15 Q. Right.

16 But if I asked, is there --

17 what affirmative evidence is there that

18 prenatal APAP use is associated with the

19 genes that cause autism, the answer is, all

20 we have is Leppart, and there's no

21 association, right?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: Again, I think

25 it's -- when you have imperfect

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1 information and you don't find an

2 association, it doesn't mean that the

3 association doesn't exist. It means

4 you were not able to find it on the

5 basis of the data that you have.

6 QUESTIONS BY MR. SNIDOW:

7 Q. Okay. For -- you still have

8 Leppart up?

9 A. I will.

10 Q. Yeah.

11 A. Yeah.

12 Q. Okay. For autism -- ADHD.

13 Sorry, for ADHD. You see in Table 2 where it

14 reports an association?

15 A. Yes.

16 Q. In Leppart here, this is what

17 you told me was the evidence that the genes

18 associated with ADHD are associated with

19 prenatal APAP use, right?

20 MR. MURDICA: Objection to

21 form.

22 THE WITNESS: This is one piece

23 of evidence in support of that

24 confounder, yes.

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. All right. What else is there?

3 A. Well, I'm just saying there is

4 one piece of evidence. I'm not -- I'm not

5 saying there's another one. I'm saying this

6 is one piece of evidence.

7 Q. I know.

8 But you're not aware of

9 anything else other than Leppart, right?

10 MR. MURDICA: Objection to

11 form.

12 THE WITNESS: I believe that

13 the ALSPAC cohort also had some data,

14 but I would want to remind myself of

15 the specifics of that.

16 QUESTIONS BY MR. SNIDOW:

17 Q. All right. We'll do that in a

18 second.

19 So for Leppart, would you --

20 the results they showed was there was a

21 risks -- odds ratio of 1.09?

22 A. Right.

23 Q. And then 1.11?

24 A. Right.

25 Q. And the confidence intervals

Page 161

1 are really close to 1, right?

2 A. What do you mean by that?

3 Q. They're 1.02 --

4 A. The lower band of the

5 confidence interval?

6 Q. Yeah. Yeah.

7 A. Yeah.

8 Q. And you would characterize that

9 as barely statistically significant?

10 A. I have characterized it as that

11 in the past.

12 Q. Yeah.

13 And you would characterize

14 those odds ratios as weak, right?

15 A. I don't know that I would ever

16 call an odds ratio weak, but they are not,

17 you know, incredibly powerful.

18 Again, remembering that what

19 the PRS captures is just a fraction of the

20 overall genetic risk. So the fact that they

21 found anything is actually quite compelling.

22 Q. Okay. All right.

23 Do you have -- do you see any

24 evidence that a mother's use of acetaminophen

25 before she gets pregnant causes autism?

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1 A. So there have been some
 2 attempts to do what we call a negative
 3 control exposure analysis to look at that
 4 very question, does prenatal use --
 5 Q. Pre-prenatal use.
 6 A. Pre-prenatal use. I'm sorry.
 7 Q. Yeah.
 8 A. Prepregnancy use.
 9 Q. Yeah.
 10 A. -- increase the risk of autism
 11 or post-pregnancy use increase the risk of
 12 autism.
 13 Q. Yeah.
 14 A. And several authors have used
 15 that design to -- in an attempt to show that
 16 it's an intrauterine effect.
 17 Q. Yeah.
 18 A. However, there are instances in
 19 this literature where the opposite was found.
 20 In fact, they showed that prepregnancy use
 21 and post-pregnancy use did have an
 22 association, which would argue for an
 23 underlying genetic or familial risk.
 24 Q. With autism diagnosis?
 25 A. Yes.

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1 Q. And what study is that?
 2 A. I'll have to go to my report to
 3 remind myself.
 4 Q. Sorry. Just to be clear, I'm
 5 asking you, you're telling me there's a study
 6 that looked at prepregnancy use and found an
 7 association with autism diagnosis?
 8 A. I need to go to my report to
 9 remind myself.
 10 Q. All right.
 11 A. There's so many studies --
 12 Q. Let's move on. At a break, I'd
 13 like you to do that.
 14 A. Okay.
 15 Q. And the same question for ADHD.
 16 Do you think that there are studies that
 17 looked at prepregnancy use? Yeah, you do.
 18 And I'm talking about ADHD
 19 diagnosis.
 20 A. Correct.
 21 Q. Okay. Not any of the screening
 22 tools.
 23 A. Well, again, I would want to
 24 review my report to make sure those are the
 25 studies that I'm talking about.

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1 Q. Yeah.
 2 A. There's five studies that used
 3 ASD diagnosis as an outcome, and eight or
 4 nine, depending on how you count, and then
 5 there are many, many others that used other
 6 outcomes.
 7 So I would want to look
 8 specifically at the studies before I answered
 9 the question.
 10 Q. All right. Why don't you do
 11 that on a break, and we'll come back to it.
 12 Put that aside for now.
 13 Okay. On page 74 of your
 14 report, you have a table of results in the
 15 literature looking at ADHD diagnosis, right?
 16 A. Correct.
 17 Q. And you chose which results to
 18 put in this table, I think?
 19 A. I did.
 20 Q. And did you make a forest plot
 21 of those results?
 22 A. No.
 23 Q. No.
 24 Well, I did. Let me show you
 25 what it looks like. All right.

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1 MR. MURDICA: Note my objection
 2 to the use of the demonstrative
 3 created by the plaintiff's lawyer.
 4 MR. SNIDOW: That's fine.
 5 That's fine.
 6 MR. MURDICA: You don't need to
 7 tell me it's fine. I'm making my
 8 objection.
 9 MR. WATTS: Overruled.
 10 QUESTIONS BY MR. SNIDOW:
 11 Q. Dr. Pinto-Martin, I'm not
 12 asking you to check every one, but take a
 13 look at the table 70 -- on 74 and 75, and let
 14 me know if you see any obvious errors in what
 15 I've done here.
 16 And I'll tell you one.
 17 Obviously, the Ystrom, the upper bound
 18 confidence interval, needs to go way, way up.
 19 I just did that so the paper wouldn't be so
 20 long.
 21 A. Sorry, I'm just checking to
 22 make sure these are accurate.
 23 Q. Yeah.
 24 A. So I haven't checked every
 25 single one, but the ones I've looked at so

Page 166

1 far --

2 Q. Looks pretty good?

3 A. Yeah.

4 Q. Okay. And you chose these

5 results, right, to include in your table?

6 A. I did.

7 Q. Yeah. If you turn -- I'm going

8 to turn to the next page, which all I've done

9 is, do you see how there's one to seven days

10 and less than eight days in Ystrom and

11 Gustavson?

12 A. Uh-huh.

13 Q. I've taken those off just to

14 show the longer-term results because --

15 otherwise, it's the same chart.

16 All right?

17 A. Okay.

18 Q. All right. So looking at this

19 study, do you agree that 100 percent of the

20 results here for long-term use of prenatal

21 APAP show a positive point estimate for the

22 risk of ADHD diagnosis?

23 MR. MURDICA: Objection to the

24 form and use of the demonstrative.

25 THE WITNESS: So when you say

Page 167

1 "looking at the study," I think you

2 mean looking at this chart that you

3 created?

4 QUESTIONS BY MR. SNIDOW:

5 Q. Yep. Sorry. Yes.

6 A. So I disagree because there are

7 two or three that show a nonsignificant

8 association.

9 Q. You know what a point estimate

10 is, right?

11 A. Right. Oh, I'm sorry, is that

12 what you asked about?

13 Q. Yeah. Can I ask it again?

14 A. So I -- yeah.

15 Q. Do you agree that 100 percent

16 of these studies had a point estimate showing

17 a positive association between prenatal APAP

18 exposure and the risk of ADHD diagnosis?

19 A. So --

20 MR. MURDICA: Objection to

21 form.

22 THE WITNESS: -- I will say

23 that I agree with that statement, and

24 I would immediately qualify it by

25 saying that a point estimate taken in

Page 168

1 isolation is meaningless in my mind.

2 First of all, we need to look

3 at the statistical significance and

4 the confidence interval associated

5 with that point estimate, and we have

6 to think about the data upon which

7 that point estimate is based.

8 QUESTIONS BY MR. SNIDOW:

9 Q. Sure.

10 So let's do the first one

11 first.

12 This one is statistically

13 significant, right?

14 MR. MURDICA: Objection. Form.

15 THE WITNESS: I'm sorry,

16 which --

17 QUESTIONS BY MR. SNIDOW:

18 Q. This one.

19 A. You're pointing to greater than

20 29 days?

21 Q. Yep.

22 A. That study reported a

23 statistically significant result for greater

24 than 29 days --

25 Q. Okay.

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1 A. -- which they then demonstrated

2 was confounded by genetics, and when they did

3 the sibling control, it was null.

4 Q. Okay. We'll get there. And I

5 included it. I included the sibling control

6 for you, right?

7 A. I see it, but you were about to

8 jump over it.

9 Q. No. No.

10 A. I wanted to point that out.

11 Q. I just wanted to say which one

12 was statistically significant. This one is?

13 A. That report of two trimesters

14 of use in the Gustavson 2021 has a

15 significant point estimate.

16 Q. Okay.

17 A. However, I think we need to

18 really characterize the data that drives

19 that. They are talking about trimesters of

20 use here based on maternal recall, and it is

21 recall, of use of APAP in the prior trimester

22 of their pregnancy. And they are then using

23 that to derive trimester-specific estimates.

24 So I would say that these data

25 are very fragile and not particularly

Page 170

1 compelling with respect to exposure.
 2 Q. Okay. That's fine. But I'm
 3 actually just asking about statistical
 4 significance, and there's one, two, three,
 5 four, five, six, seven, eight, nine -- ten
 6 more, right?
 7 MR. MURDICA: Objection to
 8 form.
 9 THE WITNESS: There are ten
 10 point estimates there that are
 11 statistically significant, and each
 12 one of them needs to be evaluated in
 13 the context of the study from which it
 14 was derived and the data that supports
 15 that purported statistically
 16 significant association.
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. Yeah.
 19 And just to get the record
 20 clear, there's actually one, two, three --
 21 sorry. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11,
 22 12 -- 13, right?
 23 MR. MURDICA: Objection to
 24 form.
 25 THE WITNESS: Again, there are

Page 171

1 13 point estimates that are
 2 statistically significant according to
 3 the evaluation done by the authors in
 4 those studies.
 5 Those authors themselves often
 6 contextualize that result to indicate
 7 that there are potential confounders
 8 and biases that could be driving the
 9 result.
 10 QUESTIONS BY MR. SNIDOW:
 11 Q. So my question is, you say in
 12 your report that you think that these results
 13 could be due to chance.
 14 Is that right?
 15 MR. MURDICA: Objection to the
 16 form.
 17 THE WITNESS: I don't recall in
 18 my report where I might have said
 19 that. It's certainly possible that
 20 that is one explanation for some of
 21 these findings --
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Okay.
 24 A. -- because many of them
 25 analyzed a multitude of specific outcomes,

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1 for example, on a screening questionnaire,
 2 individual items, sub-scales.
 3 So they are looking at many,
 4 many, many outcomes and at times not
 5 adjusting for the multiple testing, which
 6 could result in a type 1 error.
 7 Q. Right.
 8 A. So when I talk about chance,
 9 that's what I'm referring to.
 10 Q. And that's actually helpful.
 11 I wanted to clarify, though,
 12 you're not suggesting that you can get 13
 13 statistically significant results in a row
 14 due to chance, are you?
 15 MR. MURDICA: Objection to the
 16 form.
 17 THE WITNESS: I don't believe I
 18 said that anywhere in my report.
 19 QUESTIONS BY MR. SNIDOW:
 20 Q. And you don't think that?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: I can't answer
 24 that without looking specifically at
 25 each individual study and saying, is

Page 173

1 there a chance that chance explains
 2 this finding in this study, in this
 3 study. I can't do it as a whole.
 4 QUESTIONS BY MR. SNIDOW:
 5 Q. Well, you know that the chance
 6 is going to be less than .05 for all the ones
 7 that are statistically significant, right?
 8 A. That's right.
 9 Q. Okay. So the chance of a
 10 chance finding -- sorry, there's no way
 11 around chancing?
 12 A. I know.
 13 Q. Yeah. The chance of a chance
 14 finding for this result is .05?
 15 A. Correct. But look what
 16 happened once they did the sibling control,
 17 sir.
 18 Q. No, we're talking about chance
 19 right now.
 20 MR. MURDICA: It -- well, hang
 21 on. You can't do that.
 22 MR. SNIDOW: Okay.
 23 MR. MURDICA: You can't -- you
 24 can't wave her off. You can't
 25 interrupt her. That is not

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1 appropriate deposition conduct.

2 You can't wave me off either,

3 J.J. You just did what you did, and

4 you can't do that. That is improper

5 deposition conduct. Please conduct

6 yourself appropriately.

7 QUESTIONS BY MR. SNIDOW:

8 Q. The chance of a chance finding

9 for this result is less than .5, .05?

10 A. Less than .05, correct, as

11 reported in that study with the caveat that

12 we need to understand exactly where these

13 data were derived and what they --

14 Q. But the odds of that happening

15 twice, .05, .05 -- it's what, .0025?

16 MR. MURDICA: Objection to the

17 form.

18 THE WITNESS: I'm not sure that

19 you can take the chance estimate from

20 one study and apply it to another

21 study and say that, you know, there's

22 a doubling of -- a decrease by

23 100 percent of that chance.

24 I don't -- I -- we do chance

25 finding within an individual study,

Page 175

1 within an individual analysis. That's

2 the way it's done.

3 QUESTIONS BY MR. SNIDOW:

4 Q. All right. What's the odds of

5 flipping a head when you flip a coin?

6 A. 50/50.

7 Q. And what's the odds of doing

8 that twice?

9 A. 50/50.

10 Q. Right.

11 And what's the -- no. What's

12 the odds of it happening twice, heads, heads?

13 A. Oh.

14 Q. Yeah, okay. Well, I'll tell

15 you, it's .25, because you multiply the

16 probabilities together, right?

17 MR. MURDICA: Objection to

18 the --

19 THE WITNESS: You're talking

20 about flipping a coin. I'm talking

21 about an epidemiologic study that has,

22 you know, all other kinds of things

23 that we need to address when we're

24 looking at the result.

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Did you do a calculation,

3 though, to see what the likelihood of all of

4 these being due to chance was?

5 MR. MURDICA: Objection to the

6 form.

7 THE WITNESS: Again, that is

8 not my primary objection with these

9 studies that have ASD as -- ASD or

10 ADHD in this case as an outcome.

11 The bias -- I mean, the chance

12 finding was primarily directed at the

13 studies that used screening tools as

14 an outcome because of what we talked

15 about before and the multiple testing

16 and the likelihood of chance finding

17 there.

18 QUESTIONS BY MR. SNIDOW:

19 Q. All right. So the chance was

20 not your primary objection?

21 MR. MURDICA: Objection to the

22 form.

23 THE WITNESS: With respect to

24 the studies that had ADHD as an

25 outcome --

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Yeah.

3 A. -- diagnostic outcome, chance

4 was not my primary objection to the

5 credibility of the results where there was a

6 reported increased risk.

7 Rather, it was based on the

8 imprecision of the exposure, which is

9 extremely important when we're talking about

10 fetal brain development, and we need to think

11 about the timing and the dose and the

12 duration of exposure in order to be able to

13 assess whether that exposure actually had an

14 increased risk on the likelihood of autism in

15 the offspring.

16 Q. All right. Could you turn to

17 page 93 in your report?

18 A. (Witness complies.)

19 Q. All right. And do you see

20 where you say, "A Bradford Hill analysis is

21 only called for when the epidemiological

22 literature establishes an association that is

23 perfectly clearcut"?

24 A. I do.

25 Q. And then you say that you don't

<p style="text-align: right;">Page 178</p> <p>1 actually think that you should be doing a 2 Bradford Hill analysis of the ADHD literature 3 at all, right? 4 A. This is ASD, but, yes. 5 Q. Yeah. 6 And the reason why you say that 7 is because you don't think that there's an 8 association in the literature at all between 9 prenatal APAP use and ADHD, right? 10 A. I don't believe there's a 11 cred -- there's credible evidence of an 12 association between prenatal APAP use and 13 ASD. 14 Q. Well, how many studies -- how 15 many studies have to go on the forest plot 16 before you at least concede there's an 17 association? 18 I mean, look, confounding I 19 get, but how many do you need before you get 20 an association? 21 MR. MURDICA: Objection to the 22 commentary. 23 THE WITNESS: Well, I would say 24 confounding you don't get because 25 that's exactly the point here. We</p>	<p style="text-align: right;">Page 180</p> <p>1 QUESTIONS BY MR. SNIDOW: 2 Q. No, no, no. You said, "In my 3 opinion, the literature has not identified an 4 association that's perfectly clearcut and 5 beyond what we would care to attribute to the 6 play of chance." 7 Right? You said that? 8 MR. MURDICA: Objection to form 9 to the form of the question. 10 You can answer it. 11 THE WITNESS: So I put 12 "perfectly clearcut" in quotes because 13 that is a direct quote from Hill, who 14 established the Bradford Hill 15 criteria, and said in the absence of a 16 perfectly clearcut association between 17 an exposure and an outcome, Bradford 18 Hill is not warranted. 19 QUESTIONS BY MR. SNIDOW: 20 Q. Uh-huh. 21 And so my question is this, do 22 you think that these results are beyond what 23 you would care to attribute to the play of 24 chance? 25 MR. MURDICA: Objection to the</p>
<p style="text-align: right;">Page 179</p> <p>1 could have thousands of estimates of 2 an elevated risk, and if they're all 3 confounded, then in my mind that does 4 not equate with strength of an 5 association. 6 It's not about a number. It's 7 not about counting. It's about 8 evaluating each individual study and 9 the strength of the data that drives 10 the point estimate that they report. 11 I don't believe we have that 12 here. 13 QUESTIONS BY MR. SNIDOW: 14 Q. Well, I agree. It's just not 15 what you said in your report, right? 16 You said you don't think 17 there's an association because it's not, 18 quote, "Perfectly clearcut and beyond what we 19 would care to attribute to the play of 20 chance." 21 Is that what you said? 22 MR. MURDICA: Objection to the 23 form of the question. 24 THE WITNESS: I didn't say 25 that. Bradford -- Dr. Hill said that.</p>	<p style="text-align: right;">Page 181</p> <p>1 form. 2 THE WITNESS: So, again, we're 3 not talking just about chance here. 4 We're talking about the criteria of 5 Bradford Hill, and what goes into that 6 evaluation includes all of the things 7 that I mentioned before: The context 8 of the studies, the sample size, the 9 selection bias, the assessment of 10 exposure. 11 All of those things matter when 12 we're trying to establish a, 13 quote/unquote, clearcut association. 14 Because of the problems in 15 these studies, the methodologic 16 problems, I do not believe we've 17 established a clearcut association. 18 QUESTIONS BY MR. SNIDOW: 19 Q. My question is, do you think 20 these could all be due to chance? That's my 21 only question. 22 MR. MURDICA: Objection to the 23 form. 24 THE WITNESS: Again, we would 25 have to look at each study</p>

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1 individually to say whether chance
 2 might be an explanation for the
 3 finding. I can't do them as a whole.
 4 QUESTIONS BY MR. SNIDOW:
 5 Q. Okay. You've read the
 6 consensus statement, right?
 7 A. Uh-huh.
 8 Q. And did you know any of the
 9 authors?
 10 A. Not personally.
 11 Q. Any professionally?
 12 A. So Dr. Swan was a
 13 biostatistician professor when I did my
 14 doctorate at Penn -- I mean, not at Penn, I'm
 15 sorry -- at the University of
 16 California-Berkeley.
 17 Q. Did you work with her?
 18 A. She wouldn't remember me, I'm
 19 sure.
 20 Q. She wouldn't remember you?
 21 A. No. I was one student in a
 22 class.
 23 Q. But you took her class?
 24 A. I did.
 25 Q. Do you think she's an

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1 unreasonable epidemiologist?
 2 A. She's a biostatistician. I
 3 think she's, you know, a solid
 4 biostatistician from my experience with her
 5 in class.
 6 Q. And she's one of the lead
 7 authors on that consensus statement?
 8 MR. MURDICA: Objection to the
 9 form.
 10 THE WITNESS: I believe so.
 11 I'm not sure exactly where she is in
 12 the authorship, but...
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. What is -- are you aware that
 15 society for Pediatric and Perinatal
 16 Epidemiological Research, SPER, gives out an
 17 award each year?
 18 MR. MURDICA: Objection to the
 19 form.
 20 THE WITNESS: I recall that,
 21 yeah. Well, they give out several
 22 awards. They give out a student
 23 award. They give out a best paper
 24 award.
 25

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. Yep.
 3 A. Oh, yeah.
 4 Q. Rising star award?
 5 A. Yeah.
 6 Q. Do you remember that one?
 7 A. I've heard of it, yeah.
 8 Q. And do they typically give that
 9 one to good epidemiologists?
 10 MR. MURDICA: Objection to
 11 form.
 12 THE WITNESS: I have no
 13 knowledge of, you know, who evaluates
 14 that rising star, but I would imagine
 15 that they look at the individual
 16 carefully.
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. Yeah.
 19 And again, you were present at
 20 SPER, right?
 21 A. I was, back when it was first
 22 formed.
 23 Q. Outstanding organization of
 24 epidemiologists, correct?
 25 A. It's a good organization.

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1 MR. SNIDOW: Can I have YYY?
 2 Thanks.
 3 QUESTIONS BY MR. SNIDOW:
 4 Q. While she's getting that, do
 5 you know who Zeyan Liew is?
 6 A. I do not, except from reviewing
 7 the literature. I've never --
 8 Q. But you see his name in the
 9 literature?
 10 A. I've seen his name, yes.
 11 Q. He's in a lot of it, right?
 12 MR. MURDICA: Objection to
 13 form.
 14 THE WITNESS: He's written a
 15 lot of studies, yes.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. There's Liew 2014.
 18 A. 16, ABC.
 19 Q. Exactly.
 20 A. 19, yes.
 21 Q. Yep.
 22 And Olsen and Liew 2017?
 23 A. I guess I think of '16 as ABC.
 24 Maybe you're thinking C is '17.
 25 Q. Olsen and Liew, 2017?

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1 A. Oh, Olsen and Liew, yeah,
 2 different paper, yeah.
 3 Q. All right. So half a dozen
 4 studies directly on this question, right?
 5 MR. MURDICA: Objection to the
 6 form.
 7 THE WITNESS: He's written many
 8 studies on this, yes. He's written
 9 many papers. He hasn't done a study
 10 himself, but he's used data.
 11 (Pinto-Martin Exhibit 608
 12 marked for identification.)
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. All right. So I'm going to
 15 show you a printout of the SPER website.
 16 We'll mark it 608.
 17 And if you look down --
 18 MR. MURDICA: Do you have mine?
 19 MR. SNIDOW: I do not.
 20 MR. MURDICA: Thank you.
 21 QUESTIONS BY MR. SNIDOW:
 22 Q. If you look down under 2020, do
 23 you see that in 2020 they gave an honorable
 24 mention for the rising star award to
 25 Zeyan Liew?

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1 A. I do see that.
 2 Q. In 2020, that was after he had
 3 published all of the studies that we just
 4 talked through?
 5 A. That's correct.
 6 Q. And you know that he studies
 7 acetaminophen fetal development pretty much
 8 full-time, right?
 9 MR. MURDICA: Objection to
 10 form.
 11 THE WITNESS: I know nothing
 12 about what Zeyan Liew does.
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. Okay.
 15 A. But I know that he publishes
 16 studies.
 17 Q. You know he's a primary author
 18 on the consensus statement?
 19 MR. MURDICA: Objection to the
 20 form.
 21 THE WITNESS: I know he was an
 22 author. I don't know where he is in
 23 the author list.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. And then after he wrote all of

Page 188

1 those papers in 2020, SPER gave him honorable
 2 mention for the Rising Star Award?
 3 A. That looks to be the case.
 4 Q. You mentioned Dr. Swan?
 5 A. Swan, Shanna Swan.
 6 Q. Shanna Swan.
 7 A. Uh-huh.
 8 Q. Yeah. Do you think that
 9 reasonable scientists could sign on to the
 10 consensus statement?
 11 A. I do think reasonable
 12 scientists could sign on to the consensus
 13 statement because it's not -- it's not a
 14 study. It's an interpretation of the
 15 literature that some people will feel one way
 16 about and others will feel another way about.
 17 So reasonable scientists could
 18 disagree. Some could agree to sign on. Some
 19 could say no thank you.
 20 Q. Sure.
 21 The consensus statement
 22 recommends that women be warned about
 23 prenatal acetaminophen use?
 24 A. They believe that the
 25 precautionary principle should be applied

Page 189

1 here. Although they admit that the data is
 2 still quite flawed and needs to be further
 3 evaluated, they believe that the
 4 precautionary principle should be applied.
 5 That is what they said.
 6 Q. And do you think that's a
 7 reasonable view?
 8 MR. MURDICA: Objection to the
 9 form.
 10 THE WITNESS: I actually
 11 disagree with that view.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Okay.
 14 A. Because I think that the risk
 15 of denying women a pain medication during
 16 pregnancy is a significant one from a public
 17 health perspective, and I think that they
 18 overstepped the bounds of the literature that
 19 they reviewed.
 20 Remember, they did not do any
 21 of their own study or analysis. They just
 22 summarized some of the literature that
 23 existed at the time.
 24 Q. I get that you disagree, and
 25 it's kind of uncertain, but do you think it's

Page 190

1 reasonable for them to have recommended that?

2 MR. MURDICA: Objection to the

3 form.

4 THE WITNESS: I believe I

5 answered that already, and I don't

6 agree with that. I would not have

7 signed on to that statement. I think

8 that --

9 QUESTIONS BY MR. SNIDOW:

10 Q. Not asking you -- sorry. Not

11 asking you for your personal opinion.

12 What I'm saying -- let me put

13 it a different way.

14 Do you think that they were

15 being unscientific when they made that

16 recommendation?

17 MR. MURDICA: Objection to the

18 form.

19 THE WITNESS: I'm not sure what

20 you mean by "unscientific." They are

21 not evaluating primary data and

22 saying, "This is what these data

23 show." They're interpreting the

24 literature that existed at the time

25 and saying, "We think we should have

Page 191

1 applied a precautionary principle

2 here," which is their language --

3 QUESTIONS BY MR. SNIDOW:

4 Q. Yeah.

5 A. -- which really means going

6 beyond what the data shows and taking a stand

7 based on what we believe the interpretation

8 of that data should be.

9 Q. Yeah.

10 MR. MURDICA: And when you're

11 done with this area and there's not a

12 question pending, J.J., we've been

13 going an hour. It's up to you.

14 MR. SNIDOW: Okay.

15 Go off the record?

16 MR. MURDICA: Yeah.

17 MR. SNIDOW: Okay.

18 THE WITNESS: Break? Okay.

19 VIDEOGRAPHER: The time is

20 11:11 a.m., and we're off the record.

21 (Off the record at 11:11 a.m.)

22 VIDEOGRAPHER: The time is

23 11:23 a.m., and we're on the record.

24 QUESTIONS BY MR. SNIDOW:

25 Q. Okay. Dr. Pinto-Martin, during

Page 192

1 the break, were you ever able to tell me what

2 studies showed that prepregnancy use of

3 acetaminophen is associated with autism

4 diagnoses?

5 A. I'm sorry, I didn't look at

6 that.

7 Q. Okay. Will you do that next?

8 A. I'm happy to do it when we have

9 a longer break.

10 MR. MURDICA: Object to form.

11 No, you don't have to do

12 anything during the break. Nobody

13 tells you what to do.

14 You can ask your questions.

15 QUESTIONS BY MR. SNIDOW:

16 Q. If you would, I would

17 appreciate it.

18 MR. MURDICA: No. Objection.

19 That is not how depositions work.

20 J.J., you can ask questions if

21 you want. Don't tell anybody what you

22 appreciate or what you wouldn't

23 appreciate.

24 If you want to use your time

25 that way, use it.

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Have you ever published your

3 view of the evidence between prenatal

4 acetaminophen exposure and autism?

5 A. I have not published on this

6 question, no.

7 Q. So you -- have you given a

8 lecture on it?

9 A. No.

10 Q. Letter to the editor?

11 A. No.

12 Q. You can do that when you

13 disagree with a study, right?

14 A. You can do that when you

15 disagree with a study, yes.

16 Q. An editorial in a journal?

17 A. I've not done anything, no.

18 Q. Asked to speak at a conference?

19 A. No.

20 Q. Told any professional peers?

21 A. No.

22 Q. Written to any authors of these

23 journals?

24 A. I have not.

25 Q. Written to anyone on the

<p style="text-align: right;">Page 194</p> <p>1 consensus statement telling them that they're 2 wrong? 3 A. I have not. 4 Q. And why have you decided not to 5 get into this debate about whether it's 6 causal? 7 MR. MURDICA: Objection to the 8 form. 9 THE WITNESS: So I've been very 10 occupied reviewing this literature and 11 writing my expert report. I am not 12 ruling out the possibility that I 13 might write something at some point or 14 give a lecture on it at some point. 15 It's not been a focus of the 16 last, you know, six months of my life. 17 QUESTIONS BY MR. SNIDOW: 18 Q. Okay. Have you done anything 19 to make your view -- make clear your view 20 that APAP does not cause autism besides 21 serving as an expert in this case? 22 A. I have not. And, again, I'm 23 not ruling out the possibility that I would 24 do that at some point in time, but it has not 25 been the focus of my life --</p>	<p style="text-align: right;">Page 196</p> <p>1 QUESTIONS BY MR. SNIDOW: 2 Q. It's just something you said 3 before, so I thought I would ask you again. 4 You're not a neurologist, 5 right? 6 A. I am not. 7 Q. Not a neonatologist? 8 A. I am not. 9 Q. Not a toxicologist? 10 A. I am not. 11 Q. Not a teratologist? 12 A. I am not. 13 Q. Not a medical doctor? 14 A. I am not. 15 Q. Not a geneticist? 16 A. I am not. 17 Q. You don't do basic lab work? 18 A. I do not. 19 Q. You don't diagnose people with 20 autism? 21 A. I certainly am not a clinician 22 diagnosing people with autism, but as part of 23 our -- the studies that I've done, I have 24 observed probably thousands of evaluations of 25 individuals to see if they had autism.</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. Okay. 2 A. -- for the past. 3 Q. You're not a regulatory expert? 4 A. I am not. 5 Q. Not an expert on animal 6 studies? 7 A. I am not. 8 Q. Not an expert on reviewing the 9 literature on biological mechanisms? 10 A. So biological mechanisms are 11 typically based on animal studies, and so the 12 same answer applies. I'm not an expert in 13 animal studies. 14 Q. Not an expert on biological 15 plausibility? 16 MR. MURDICA: Objection to 17 form. 18 THE WITNESS: So I understand 19 the criterion of biological 20 plausibility, and when I believe it's 21 important to explore the literature 22 associated with biological 23 plausibility, I do so. But that's 24 a -- I don't know who an expert on 25 biological plausibility would be.</p>	<p style="text-align: right;">Page 197</p> <p>1 Q. So, no, you don't diagnose it? 2 MR. MURDICA: Objection. 3 THE WITNESS: I do not make the 4 diagnosis, no. 5 QUESTIONS BY MR. SNIDOW: 6 Q. And same for ADHD, you don't 7 not diagnose them? 8 A. I am not a clinician. I do not 9 make diagnoses. 10 Q. You also don't treat people 11 with autism or ADHD? 12 A. I'm not a clinician, so I do 13 not treat. 14 Q. But you're definitely an expert 15 in autism, right? 16 A. I'm an epidemiologist, a 17 peri-epidemiologist specifically, and I have 18 spent my career studying the etiology of 19 autism spectrum disorder. 20 Q. How about ADHD? 21 A. So ADHD is another 22 neurodevelopmental disorder, and I have 23 studied it in its relation to autism because 24 the differentiation between those two and the 25 etiology differences between those two is</p>

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1 important to my work.

2 Q. Have you published on it?

3 A. There's certainly publications

4 of mine that have ADHD in them, but it's

5 not -- again, not my primary focus. My

6 research has been funded to specifically look

7 at autism spectrum disorders in the study to

8 explore early development, which is the

9 CDC-funded study that I've been involved in

10 for many years. The -- one of the comparison

11 groups is other developmental disabilities,

12 not autism, and in that comparison group, are

13 children with ADHD.

14 Q. Okay. Let's talk about

15 confounders again for a moment.

16 In your report you say that the

17 confounding variable to be a confounder needs

18 to be independently associated with the

19 outcome, right?

20 A. Correct.

21 Q. And you defined that as a risk

22 factor.

23 A. Define what as a risk factor,

24 I'm sorry.

25 Q. Whether it's independently

Page 199

1 associated with the outcome, you say it's a

2 risk factor.

3 A. It's a potential risk factor if

4 it's independently associated with the

5 outcome. That's what we're exploring in an

6 assessment of confounding.

7 Q. Okay. And you say that the

8 confounder must not lie on the causal pathway

9 between exposure and disease?

10 A. Correct. Correct.

11 Q. And do you agree it's

12 theoretically possible that genetics

13 predispose a woman to take acetaminophen and

14 that the acetaminophen causes the autism?

15 MR. MURDICA: Objection to the

16 form.

17 THE WITNESS: So I'm not sure I

18 understand your question.

19 QUESTIONS BY MR. SNIDOW:

20 Q. All right. Hold on. Let me --

21 A. I think you're talking about a

22 causal pathway.

23 Q. If you don't understand, let me

24 ask again.

25 A. Yeah.

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1 Q. You say, "Must not lie on the

2 causal pathway between exposure and disease."

3 Right?

4 MR. MURDICA: Objection to the

5 form.

6 And I'd appreciate it if you

7 didn't do this hand waving thing while

8 she's in the middle of speaking again.

9 Thank you.

10 MR. SNIDOW: Okay. I'll put my

11 hands down.

12 QUESTIONS BY MR. SNIDOW:

13 Q. You say, "Must not lie on the

14 causal pathway between exposure and disease,"

15 right?

16 A. In order for a variable to be a

17 confounder, it cannot lie on the causal

18 pathway between exposure and disease.

19 Q. And I'll give you an example.

20 So secondhand smoke, right?

21 A. Right.

22 Q. You know that's causally

23 associated with lung cancer, right?

24 A. That has been established, yes.

25 Q. And there was, I think, some

Page 201

1 question about whether that was confounded by

2 socioeconomic status; is that right?

3 A. I'm not familiar with that

4 literature, but --

5 Q. Well, you talk about it in your

6 report, don't you?

7 A. Yeah. I mean, I just don't

8 know the study that you're referring to and

9 so --

10 Q. Well, in your report you say

11 it's stronger than the Tylenol literature,

12 right?

13 MR. MURDICA: Objection. You

14 cut her off again.

15 THE WITNESS: Can you point to

16 me to exactly what you're talking

17 about? Smoking and lung cancer is a

18 stronger --

19 QUESTIONS BY MR. SNIDOW:

20 Q. Secondhand smoke. You reviewed

21 that literature?

22 MR. MURDICA: Objection to the

23 form.

24 Is that a question?

25

<p style="text-align: right;">Page 202</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Yeah.</p> <p>3 Did you review that literature?</p> <p>4 A. I have certainly reviewed that</p> <p>5 literature in the course of my work as an</p> <p>6 epidemiologist, and I don't remember if I</p> <p>7 referred -- reviewed it specifically for this</p> <p>8 report.</p> <p>9 Q. Okay.</p> <p>10 A. If I referred to something, it</p> <p>11 was based on my general knowledge.</p> <p>12 Q. Well, let me refresh your</p> <p>13 memory because you have some footnotes on it.</p> <p>14 Can you go to page 55?</p> <p>15 At the top there, you see you</p> <p>16 talk about secondhand smoke?</p> <p>17 A. Uh-huh.</p> <p>18 Q. And do you see there you say</p> <p>19 that the literature is stronger than it is</p> <p>20 for Tylenol, right?</p> <p>21 MR. MURDICA: Objection to the</p> <p>22 form.</p> <p>23 THE WITNESS: So I say that</p> <p>24 there were 50 consistent epidemiologic</p> <p>25 studies, and I'm now recalling that</p>	<p style="text-align: right;">Page 204</p> <p>1 you cite is the Surgeon General, right?</p> <p>2 A. That's correct.</p> <p>3 MR. SNIDOW: Can I have BBBB,</p> <p>4 four Bs? It's in the back there.</p> <p>5 QUESTIONS BY MR. SNIDOW:</p> <p>6 Q. Okay. All right. I'm showing</p> <p>7 you an excerpt from the Surgeon General's</p> <p>8 report on secondhand smoke. It is, again, in</p> <p>9 its full version, more than -- at least 700</p> <p>10 pages, so I've got an excerpt for you.</p> <p>11 MR. SNIDOW: But, Jim, this one</p> <p>12 is Googleable. You can use the Google</p> <p>13 machine, as my colleague put it</p> <p>14 recently.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. All right. Before we look into</p> <p>17 this, Dr. Pinto-Martin, do you know what the</p> <p>18 Surgeon General's estimate for the risk ratio</p> <p>19 for secondhand smoke and lung cancer was?</p> <p>20 A. I do not off the top of my</p> <p>21 head, but I imagine I could find it in here.</p> <p>22 Q. Yeah, you can.</p> <p>23 So if you go to page 434.</p> <p>24 All right. Do you see that?</p> <p>25 A. I see page 434, yeah.</p>
<p style="text-align: right;">Page 203</p> <p>1 I -- that I looked at that in response</p> <p>2 to Dr. Baccarelli who said that, you</p> <p>3 know, a weak association can</p> <p>4 ultimately prove causal, something</p> <p>5 that I don't disagree with.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. Yeah.</p> <p>8 But you do think it's stronger,</p> <p>9 don't you?</p> <p>10 MR. MURDICA: Objection.</p> <p>11 THE WITNESS: Stronger than</p> <p>12 what?</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. Than the association between</p> <p>15 prenatal APAP exposure and autism, Doctor.</p> <p>16 A. Yes, I do.</p> <p>17 Q. Okay. And I just want to ask</p> <p>18 because I'm -- I wasn't real sure. You did</p> <p>19 look at that literature before writing this</p> <p>20 report?</p> <p>21 A. I certainly -- when I saw that</p> <p>22 in Dr. Baccarelli's report, I went and</p> <p>23 reminded myself what was there, and I looked</p> <p>24 up a reference and cited that reference.</p> <p>25 Q. Okay. And the reference that</p>	<p style="text-align: right;">Page 205</p> <p>1 Q. It says, "Secondhand smoke</p> <p>2 exposure from spouses, an update in the</p> <p>3 literature, reports Hackshaw obtains a RR of</p> <p>4 1.24."</p> <p>5 Right?</p> <p>6 A. I'm sorry, where are you</p> <p>7 looking? Oh, Hackshaw and colleagues pooled</p> <p>8 1997?</p> <p>9 Q. Yeah.</p> <p>10 A. '97 published studies. Yep.</p> <p>11 Q. 1.24?</p> <p>12 A. I see that.</p> <p>13 Q. And then they quote Zhong,</p> <p>14 1.20?</p> <p>15 A. Correct.</p> <p>16 Q. Then if you turn to 436, they</p> <p>17 actually show a lot of studies.</p> <p>18 A. Uh-huh.</p> <p>19 Q. Do you see them there?</p> <p>20 A. I see a whole list of studies,</p> <p>21 yeah.</p> <p>22 Q. All right. And any of those</p> <p>23 studies show a risk ratio above 2.0?</p> <p>24 A. Do you want me to look at them</p> <p>25 one at a time?</p>

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1 Q. It should be pretty easy.

2 A. Not -- not that I see, no.

3 Q. Okay. All -- if you look down

4 at childhood exposure?

5 A. I'm sorry, where is that?

6 Q. Childhood exposure at the

7 bottom.

8 A. Oh, now we're -- oh, we're at

9 the next page, sorry. You jumped -- got it.

10 Oh, yeah, you're showing me here. Okay.

11 MR. MURDICA: No, you can

12 look --

13 THE WITNESS: Okay.

14 QUESTIONS BY MR. SNIDOW:

15 Q. Do you see that?

16 A. Yeah.

17 Q. For childhood exposure, none of

18 them are above 2.0?

19 A. Correct.

20 Q. The ones I've highlighted are

21 statistically nonsignificant?

22 A. Correct.

23 Q. There's one of the results that

24 shows a statistically significant protective

25 effect, right, that Europe, six studies?

Page 207

1 A. Yeah.

2 Q. Okay. Do you still think that

3 the relationship between secondhand smoke and

4 lung cancer is causal?

5 MR. MURDICA: Objection to the

6 form.

7 THE WITNESS: The data here in

8 some instances, you've cited a bunch

9 of different numbers and relative

10 risks and odds ratios here.

11 But in general, it looks to me

12 like the secondhand smoke exposure

13 from spouses is consistent, and the

14 childhood smoke exposure is less

15 consistent.

16 QUESTIONS BY MR. SNIDOW:

17 Q. Okay. Would you say

18 inconsistent if you looked at that?

19 A. So, again, as I've -- as I've

20 described to you, my evaluation and

21 consistency is very importantly informed by

22 the underlying data.

23 And I have no idea in this set

24 of studies here -- this is a meta-analysis,

25 which includes many studies -- how they

Page 208

1 derived the exposure information, and so it's

2 really hard for me to comment on that.

3 Q. But you wouldn't say that just

4 because they had these statistically

5 nonsignificant results, that means no

6 causation, would you?

7 MR. MURDICA: Object to the

8 form.

9 THE WITNESS: Again, without

10 knowing the specifics of the study,

11 I think we need to look carefully at

12 what might have an impact on that,

13 what was the sample size, how did they

14 measure exposure.

15 QUESTIONS BY MR. SNIDOW:

16 Q. Yeah, sorry. Let me just take

17 a step back.

18 You think that secondhand smoke

19 causes lung cancer, do you not?

20 A. I think that there is good

21 evidence to support a causal association

22 between secondhand smoke and lung cancer.

23 Q. And you agree that many of

24 these studies are statistically

25 insignificant, right?

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1 A. Many of these studies looking

2 at childhood exposure are statistically

3 insignificant, yes.

4 Q. Well, here's the one for

5 workplace exposure. We get two statistically

6 insignificant results there, right?

7 MR. MURDICA: Object to the

8 form, and if that's intended to be a

9 demonstrative, to the use of the

10 demonstrative.

11 QUESTIONS BY MR. SNIDOW:

12 Q. Is that right?

13 A. I see two statistically

14 insignificant results, yes.

15 Q. And you still think this is a

16 causal association, right?

17 MR. MURDICA: Object --

18 objection to the form.

19 THE WITNESS: I still think the

20 weight of the evidence supports a

21 causal association between secondhand

22 smoke and lung cancer.

23 QUESTIONS BY MR. SNIDOW:

24 Q. Okay.

25 A. I think that the situation with

Page 210

1 secondhand smoke is a very different
 2 situation from what we have with respect to
 3 APAP in terms of the precision of the
 4 exposure.
 5 Q. Yeah. Sure.
 6 Let's look at the childhood
 7 one. I guess I should ask, do you think that
 8 childhood secondhand smoke exposure causes
 9 lung cancer?
 10 A. I've never --
 11 MR. MURDICA: Objection to the
 12 form.
 13 THE WITNESS: Yeah. I've never
 14 reviewed that literature specifically,
 15 so I'm not willing to offer an opinion
 16 without looking at the individual
 17 studies and evaluating --
 18 QUESTIONS BY MR. SNIDOW:
 19 Q. Let's look at page 445 of what
 20 you've got in front of you.
 21 Do you see the Surgeon General
 22 there, Conclusions, 1?
 23 A. Yes.
 24 Q. It says, "The evidence is
 25 sufficient to infer a causal relationship

Page 211

1 between secondhand smoke exposure and lung
 2 cancer among lifetime smokers. This
 3 conclusion extends to all secondhand smoke
 4 exposure regardless of location."
 5 A. I see that.
 6 Q. Okay. You can put that aside
 7 for now.
 8 So let me ask you this. This
 9 childhood exposure forest plot, do you think
 10 that's stronger or weaker than this one?
 11 MR. MURDICA: Objection to the
 12 form.
 13 THE WITNESS: Again, I think
 14 just comparing point estimates across
 15 two entirely different exposures and
 16 outcomes is a misguided exercise.
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. That's fine.
 19 It's not just point estimates,
 20 though, right? It's confidence intervals,
 21 too?
 22 A. Same point.
 23 Q. Yeah, okay.
 24 But can you tell me for the --
 25 for the consistency of the findings, would

Page 212

1 you say this one is the more positive
 2 association or this one is the more
 3 consistent positive association?
 4 MR. MURDICA: Objection to the
 5 form.
 6 THE WITNESS: Again, you're
 7 asking me to look at two forest plots
 8 and make an evaluation that requires
 9 much more information in order to be
 10 precise about my response.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Even to tell me if there's a
 13 consistent association? I'm not asking about
 14 causation.
 15 MR. MURDICA: Same objection.
 16 THE WITNESS: You're asking me
 17 to compare different bodies of
 18 evidence, one on smoking and one on
 19 acetaminophen. They are entirely
 20 different in the underlying data.
 21 And I can't evaluate them with
 22 respect to their relevant consistency.
 23 I'm just not willing to do that.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. Right.

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1 But the presence of this no
 2 result here, or actually statistically
 3 significant protective effect, doesn't
 4 preclude you from making a causal inference,
 5 does it?
 6 MR. MURDICA: Objection to the
 7 form.
 8 THE WITNESS: I'm sorry, can
 9 you -- can you --
 10 QUESTIONS BY MR. SNIDOW:
 11 Q. Yeah.
 12 A. -- rephrase that?
 13 Q. This is the literature on
 14 childhood exposure and lung cancer, right?
 15 A. That's what you are presenting,
 16 yes.
 17 Q. You think it's causal, right?
 18 A. I believe there is evidence in
 19 support of a causal association between
 20 prenatal smoking -- I mean, I'm sorry,
 21 secondhand smoking and --
 22 Q. Yeah.
 23 A. -- and cancer.
 24 Q. And yet, one of the results
 25 they got was statistically significant in the

Page 214

1 wrong direction, right?

2 A. So one result from Europe, I

3 don't know what's included there, appears to

4 have a protective effect.

5 Q. And that's all I'm asking.

6 That happens sometimes, right? Even with

7 true causal exposure, sometimes you get a

8 blip result, don't you?

9 MR. MURDICA: Objection to the

10 form.

11 THE WITNESS: I don't know if

12 it's a blip result. I don't know what

13 the data is based on, but that is a

14 different result from the others, I

15 will grant you that.

16 QUESTIONS BY MR. SNIDOW:

17 Q. That's what I'm asking. Thank

18 you.

19 All right. You agree that a

20 number of people on the other side of the

21 debate from you in this literature have said

22 that causation is the most likely

23 explanation?

24 A. So when you say "people on the

25 other side of the debate," I'm not quite sure

Page 215

1 who you mean.

2 Q. Okay.

3 A. If you can give me an example

4 of a specific person that disagrees with my

5 conclusion, I'd be happy to --

6 Q. Yeah.

7 A. -- to think about that, but

8 that's a broad statement, and I don't have a

9 response.

10 (Pinto-Martin Exhibit 609

11 marked for identification.)

12 QUESTIONS BY MR. SNIDOW:

13 Q. Can I just have tab H?

14 Oh, gosh. All right. This,

15 I'm going to mark, as Exhibit 609, which is

16 Olsen and Liew 2017.

17 And you read this paper when

18 writing your report, right?

19 A. I did.

20 Q. All right. If you turn to

21 page 1395, do you see there's a paragraph

22 that says, "The existing evidence"?

23 A. 1395.

24 Q. It's just the first page.

25 A. Okay.

Page 216

1 Q. The first --

2 A. Existing evidence, yeah.

3 Q. And it says -- and I've got the

4 monitor if you want.

5 It says, "The existing evidence

6 is based on observational data from several

7 cohorts."

8 Do you agree with that?

9 A. I do.

10 Q. It says, "Different analytical

11 options have been used."

12 Agree with that?

13 A. Uh-huh.

14 Q. It says, "These research

15 findings have increased the probability that

16 the association is causal."

17 Do you see that?

18 A. I see that.

19 Q. Do you agree with that one?

20 A. Not necessarily.

21 Q. Do you think it's a possibly

22 correct thing to say?

23 A. It's certainly not something

24 that I would say, again, because I'm not

25 willing to say that something is causal based

Page 217

1 on observational studies --

2 Q. I see.

3 A. -- observational data.

4 Q. And these guys have, it sounds

5 like, a lower threshold for causation than

6 you do, right?

7 A. I would say that, yeah, or they

8 interpret that concept differently.

9 Q. And do you agree that it was

10 reasonable to say that "the findings

11 increased the probability that the

12 association is causal"?

13 MR. MURDICA: Objection to the

14 form.

15 THE WITNESS: Again, I think

16 that is their interpretation.

17 My assessment based on the

18 methodologic problems with the study

19 is not consistent with that.

20 QUESTIONS BY MR. SNIDOW:

21 Q. But would you -- would you say

22 that they're being quacks for saying that?

23 MR. MURDICA: Objection to the

24 form.

25 THE WITNESS: Again, I don't

Page 218

1 know what a quack is, and I don't use
 2 that term. I find it somewhat
 3 derogatory.
 4 I think that every
 5 epidemiologist is doing their best to
 6 interpret the evidence on a very
 7 important issue to the best of their
 8 ability using the training that they'd
 9 received and the way that they think
 10 about establishing causality.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Right.
 13 And you applied that analysis
 14 to this statement here when they say,
 15 "Increase the probability that the
 16 association was causal"?
 17 MR. MURDICA: Objection to the
 18 form.
 19 THE WITNESS: I believe that
 20 they were using their own training and
 21 their own interpretation to come up
 22 with that statement.
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Okay.
 25 A. It's not something that I would

Page 219

1 say.
 2 Q. Yeah. No, I get it.
 3 And that's exactly what I mean.
 4 I know you disagree, but I'm asking if that's
 5 within the realm of reasonable debate?
 6 MR. MURDICA: Objection to the
 7 form.
 8 THE WITNESS: Yeah. I wouldn't
 9 call it debate, but I think it's
 10 interpretation, and people -- I would
 11 say that trained epidemiologists can
 12 interpret evidence differently.
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. Including the evidence that
 15 they're describing here?
 16 A. Including the evidence that
 17 they're describing here.
 18 MR. MURDICA: Object to form.
 19 QUESTIONS BY MR. SNIDOW:
 20 Q. And then he goes on to say,
 21 "It's too simple and not justified to explain
 22 away the possibility of confounding" --
 23 excuse me, I'll say it again. I screwed it
 24 up totally.
 25 He goes on to say, "It is too

Page 220

1 simple and not justified to explain away the
 2 possibility of causality by mentioning
 3 confounding."
 4 Do you see that?
 5 A. I see that he says that, yes.
 6 Q. And do you agree?
 7 A. I do not.
 8 Q. Okay. So you think it's fine
 9 to just mention confounding?
 10 A. I'm not sure I understand your
 11 question. I think we must consider the
 12 possibility of confounding and look carefully
 13 at the possibility that confounding explains
 14 some or all of the association.
 15 Q. Okay. But you need actual
 16 evidence of confounding before explaining
 17 away the possibility of causality, don't you?
 18 A. You need evidence on the
 19 confounder that you're testing, and you need
 20 to be able to assess its impact on the
 21 results that you have reported, yes.
 22 Q. And you need evidence both that
 23 it's associated with the outcome and that
 24 it's associated with the exposure, right?
 25 A. Correct.

Page 221

1 Q. Correct.
 2 Okay. Let's look at -- ah,
 3 same one. 1396, which is the next page.
 4 All right. Do you see where it
 5 says, "The studies we are aware of covering
 6 the topic of fetal programming all find
 7 statistically significant results"?
 8 A. I do.
 9 Q. Okay. It says, "But that plays
 10 a limited role in our reading and
 11 interpretation of the data."
 12 Right?
 13 A. That's what they say.
 14 Q. And you'd agree with that,
 15 right? That's what you've been telling me
 16 all morning?
 17 MR. MURDICA: Objection to the
 18 form.
 19 THE WITNESS: Not exactly sure
 20 what they're referring to there, if
 21 they're talking about mechanisms of
 22 action. I think -- I agree that I
 23 give it limited weight in my
 24 evaluation.
 25

Page 222

1 QUESTIONS BY MR. SNIDOW:
 2 Q. Yeah.
 3 They go on to say, "More
 4 important is the methods and bias analyses
 5 that have been applied trying to make the
 6 association go away."
 7 Right? They say that?
 8 A. They say that, yes.
 9 Q. And do you agree that
 10 researchers in this field have tried to make
 11 the association go away?
 12 A. I think that's perhaps
 13 mischaracterizing it. I don't think we try
 14 to make an association go away. When we are
 15 doing an epidemiologic study, we evaluate the
 16 impact of potential confounders and biases on
 17 that measure of association to see whether
 18 it's credible.
 19 Q. And do you see it says,
 20 "Comparison of exposure periods during and
 21 after" -- next page -- "pregnancy makes the
 22 case" -- "makes the case her own control
 23 could also help eliminate bias"?
 24 A. So I know they're referring
 25 there to a negative control as we talked

Page 223

1 about before --
 2 Q. Yeah.
 3 A. -- using women prepregnancy
 4 and after pregnancy.
 5 Q. Yeah.
 6 A. And I would argue that that --
 7 using that as a negative control has
 8 problems.
 9 Q. Uh-huh.
 10 A. Because we know that pregnancy
 11 changes a woman in all kinds of way, right,
 12 physical ways and her -- and perhaps could
 13 influence the pain that she's experiencing,
 14 her willingness to take a pain medication,
 15 and her necessity of taking acetaminophen as
 16 opposed to another medication that perhaps is
 17 no longer indicated during pregnancy.
 18 Q. Yeah.
 19 A. So using the woman as her own
 20 negative control I think has some problems.
 21 Q. Okay. But I'm just asking,
 22 it's been done, right? They've done that.
 23 8 refers to the Stergiakouli
 24 study. You know they did it in that one?
 25 A. They did that in the

Page 224

1 Stergiakouli study. However, can I just
 2 point out that the Stergiakouli results that
 3 are reported in the main paper are the
 4 unadjusted results?
 5 And when you look at the
 6 adjusted results in the supplementary table,
 7 they actually support the notion of
 8 unmeasured confounding.
 9 Q. Okay. Did you write to Olsen
 10 and Liew to tell them that, that they got
 11 Stergiakouli wrong here?
 12 MR. MURDICA: Objection to the
 13 form.
 14 THE WITNESS: Again, as I've
 15 said before, that has not been the
 16 focus of the past six months of my
 17 life, but I am not ruling out the
 18 possibility that I would write a
 19 letter to the editor or to express my
 20 opinions about it at some point in
 21 time.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Okay. I hope you do.
 24 Do you see where it says
 25 "triangulation" here?

Page 225

1 A. I'm sorry, I lost the spot
 2 where you are.
 3 Q. Do you see where it says "it's
 4 a term used to address a bias problem as
 5 approached from different angles"?
 6 A. Yes, I see that.
 7 Q. And you agree that's been
 8 employed here?
 9 A. So I think what they're
 10 referring to here is looking at the cohort
 11 results and comparing it to the negative
 12 control exposure results, yes.
 13 Q. Right.
 14 So they've done that here?
 15 A. They have done that.
 16 Q. Okay.
 17 A. Well, I guess that's what
 18 they're saying here.
 19 Q. Yeah.
 20 And then it says -- it quotes
 21 Arthur Conan Doyle. It says, "Once you
 22 eliminate the impossible, whatever remains,
 23 no matter how improbable, must be the truth."
 24 A. I've seen that quote before.
 25 Q. Yeah. It's in Bradford Hill,

<p style="text-align: right;">Page 226</p> <p>1 right?</p> <p>2 A. It's in Bradford Hill, and it's</p> <p>3 in Baccarelli's report, yes.</p> <p>4 Q. Yeah. Well, it's in Bradford</p> <p>5 Hill.</p> <p>6 And then it says, "Such</p> <p>7 attempts have so far been unsuccessful."</p> <p>8 Right?</p> <p>9 A. That's what it says.</p> <p>10 Q. And that's saying that they've</p> <p>11 tried to find evidence for other explanations</p> <p>12 other than causation and at least as of 2017,</p> <p>13 no luck, right?</p> <p>14 A. I disagree with that statement.</p> <p>15 As I just pointed out in the Stergiakouli,</p> <p>16 for example, when they used a negative</p> <p>17 control exposure, both paternal and maternal</p> <p>18 prepregnancy use showed an increased risk of</p> <p>19 autism in the offspring, which supports the</p> <p>20 notion of familial or genetic confounding.</p> <p>21 Q. Yeah, I know you disagree. I</p> <p>22 was actually just trying to get an</p> <p>23 interpretation of the sentence.</p> <p>24 They're saying they've tried to</p> <p>25 eliminate other explanations, and those</p>	<p style="text-align: right;">Page 228</p> <p>1 would show no confounding, it shows</p> <p>2 there is confounding, and the same</p> <p>3 with paternity use.</p> <p>4 QUESTIONS BY MR. SNIDOW:</p> <p>5 Q. Could you do that on a break</p> <p>6 for me on as well?</p> <p>7 MR. MURDICA: Objection to the</p> <p>8 form.</p> <p>9 If you want her to do</p> <p>10 something --</p> <p>11 THE WITNESS: I'm happy to look</p> <p>12 through my report and come up with</p> <p>13 them. I'm not going to try and do it</p> <p>14 from memory.</p> <p>15 MR. SNIDOW: Thank you. That's</p> <p>16 all I'm asking.</p> <p>17 THE WITNESS: And I can do it</p> <p>18 right now.</p> <p>19 (Pinto-Martin Exhibit 610</p> <p>20 marked for identification.)</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. I'm going to -- I'm going to</p> <p>23 show you another study that I'm going to mark</p> <p>24 as Exhibit 610, which is the Gou paper.</p> <p>25 All right. And you've read</p>
<p style="text-align: right;">Page 227</p> <p>1 attempts have been unsuccessful, right?</p> <p>2 MR. MURDICA: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: I see the</p> <p>5 sentence as it's written, and I'm</p> <p>6 saying I disagree with that statement.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Okay.</p> <p>9 A. Because I think that the</p> <p>10 attempts actually have demonstrated residual</p> <p>11 confounding.</p> <p>12 Q. Okay. And that's Stergiakouli?</p> <p>13 A. That's one example, yes.</p> <p>14 Q. All right. Why don't you just</p> <p>15 give them all to me right now.</p> <p>16 What else?</p> <p>17 MR. MURDICA: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: I can't just</p> <p>20 rattle them off. I can look through</p> <p>21 the studies and describe where the</p> <p>22 negative control exposures or the</p> <p>23 maternal pre and post-pregnancy use</p> <p>24 have resulted in an increased risk in</p> <p>25 spite of the proposition that that</p>	<p style="text-align: right;">Page 229</p> <p>1 this one, right?</p> <p>2 A. Yes, this is a meta-analysis.</p> <p>3 Q. It is a meta-analysis.</p> <p>4 If we turn to page 204.</p> <p>5 Are you there?</p> <p>6 A. I am there.</p> <p>7 Q. It says, "These are validated,</p> <p>8 large prospective cohort studies and includes</p> <p>9 some analytical methods such as</p> <p>10 sibling-controlled analyses."</p> <p>11 Right?</p> <p>12 A. Correct.</p> <p>13 Q. And this is before Gustavson,</p> <p>14 to be fair, right? So they don't cite it.</p> <p>15 A. Right.</p> <p>16 Q. But they do cite Brandlistuen,</p> <p>17 right?</p> <p>18 A. Right.</p> <p>19 Q. And that's a sibling-control</p> <p>20 study that showed a result even after doing</p> <p>21 the sibling controls?</p> <p>22 A. That's correct, although</p> <p>23 Brandlistuen was based on a nondiagnostic</p> <p>24 outcome --</p> <p>25 Q. Right.</p>

Page 230

1 A. -- so...

2 Q. And you don't like those,

3 right?

4 A. It's not that I don't like

5 them.

6 MR. MURDICA: Objection.

7 THE WITNESS: I just don't

8 think they are contributory to my

9 opinion about the association between

10 prenatal APAP exposure and the

11 diagnosis of autism or ADHD.

12 QUESTIONS BY MR. SNIDOW:

13 Q. Yeah, and that's fair.

14 Then the Gou authors go on to

15 say, "The most recent set of studies have

16 consistently suggested a moderately increased

17 risk from in utero acetaminophen exposure."

18 Right?

19 A. That's what they say.

20 Q. And they say, "These research

21 findings lend weight to the hypothesis that

22 the association is causal."

23 Right?

24 A. That's right. They're saying

25 there's a hypothesis and the evidence is

Page 231

1 supporting the hypothesis of causality, but

2 it's still a hypothesis.

3 Q. Right. No, I get it.

4 And I'm not asking you on the

5 overall causation question, but do you think

6 that's a reasonable thing for them to have

7 said here?

8 MR. MURDICA: Objection to the

9 form.

10 THE WITNESS: So, again, a

11 meta-analysis is taking, you know,

12 data that already exists. They

13 don't -- they can't control how the

14 data was collected and what the

15 reliability of that information is.

16 So given that caveat, that they're

17 basing it on studies of that

18 methodologic flaws and acknowledging

19 that caveat, I think it's a reasonable

20 statement.

21 QUESTIONS BY MR. SNIDOW:

22 Q. Okay. And then they say, "It's

23 overly simplistic and not justifiable to

24 explain away the possibilities of causality

25 through confounding factors alone."

Page 232

1 Right?

2 MR. MURDICA: Objection to

3 form.

4 THE WITNESS: I'm not sure I

5 agree with that statement.

6 QUESTIONS BY MR. SNIDOW:

7 Q. Okay. Do you think it's

8 reasonable for them to say it?

9 MR. MURDICA: Objection to the

10 form.

11 THE WITNESS: I think if I

12 wanted to answer that, I would want to

13 read, you know, a couple of pages of

14 this to really see where that's coming

15 from. You're sort of pulling it out

16 of context. I'm not sure exactly what

17 they're trying to say there. So it's

18 a little hard to react to a single

19 statement like that.

20 QUESTIONS BY MR. SNIDOW:

21 Q. Okay. And then they call out

22 confounding by indication in particular,

23 right?

24 A. They do.

25 (Pinto-Martin Exhibit 611

Page 233

1 marked for identification.)

2 QUESTIONS BY MR. SNIDOW:

3 Q. All right. Let's look at J,

4 which I'm going to mark as 611.

5 All right. And this one is

6 Stergiakouli 2016?

7 A. It is.

8 Q. If you turn to page 967.

9 All right. And do you see at

10 the bottom there it says, "These findings,

11 when coupled with those from the previous

12 discordant sibling-design study, suggests

13 that the association between prenatal

14 acetaminophen exposure and childhood

15 behavioral problems is not explained by

16 unmeasured familial factors linked to both

17 acetaminophen use and childhood behavioral

18 problems"?

19 A. I see that statement.

20 Q. Yeah.

21 A. And I think that that statement

22 is actually a mischaracterization of the

23 data. Because as I stated, if you pull the

24 supplementary tables --

25 Q. Yeah.

<p style="text-align: right;">Page 234</p> <p>1 A. -- the effect in paternal use 2 is actually greater than the effect in 3 maternal prenatal use. 4 And this study had a whole set 5 of commentaries that came following it 6 because people actually accused her of 7 mischaracterizing the data. 8 So I -- 9 Q. Yeah. 10 A. -- I see that statement, but I 11 think that it's not a fair summary of the 12 data that she evaluated. 13 MR. MURDICA: Let me just add 14 before you ask another question. 15 You have this tendency to 16 comment while she's giving answers and 17 to say, yeah, yeah, or other things, 18 and I'm sure it's unintentional, but 19 it's distracting, and I don't think 20 it's the right thing to do. 21 So if you could try to stop it, 22 I'd appreciate it. 23 MR. SNIDOW: Okay. It wasn't 24 intentional. 25 MR. MURDICA: I said I don't</p>	<p style="text-align: right;">Page 236</p> <p>1 A. I do not think it's a 2 reasonable thing to say because a negative 3 control analysis is designed to address that 4 question specifically: Is the effect an 5 intrauterine effect? If so, you should not 6 see an effect prepregnancy or post-pregnancy. 7 You should not see an effect by paternal use. 8 And in her supplementary 9 tables, she reports both. 10 (Pinto-Martin Exhibit 612 11 marked for identification.) 12 QUESTIONS BY MR. SNIDOW: 13 Q. Uh-huh. D is going to be 14 marked as -- 15 (Off the record discussion.) 16 MR. SNIDOW: And will you make 17 sure that one is not highlighted. 18 THE WITNESS: It's highlighted. 19 MR. SNIDOW: It is? Trade me. 20 MR. MURDICA: He wants to 21 trade. 22 THE WITNESS: Well, now I don't 23 have one. 24 MR. SNIDOW: I know. I want 25 you to have the real one.</p>
<p style="text-align: right;">Page 235</p> <p>1 think it's intentional. I think it's 2 just a tick that you have. 3 MR. SNIDOW: Uh-huh, all right. 4 MR. MURDICA: Just try not to 5 do it. 6 QUESTIONS BY MR. SNIDOW: 7 Q. All right. Are you ready, 8 Doctor? 9 A. I am. 10 Q. Okay. What you're suggesting 11 is that the authors of this study 12 mischaracterized their own data? 13 A. I am. 14 Q. Okay. You see here where it 15 says, "The findings are consistent with an 16 intrauterine effect"? 17 A. I'm sorry, what page are you 18 on? 19 Q. On 967, right at the bottom. 20 A. Right-hand column. Okay. 21 Q. You see it says, "The findings 22 are consistent with an intrauterine effect"? 23 A. Yes, I see that. 24 Q. Do you think that's a 25 reasonable thing to say?</p>	<p style="text-align: right;">Page 237</p> <p>1 There you go. 2 THE WITNESS: Thank you. 3 MS. KO: J.J., do you happen to 4 have an extra copy for me? 5 MR. SNIDOW: I do. 6 MS. KO: Thank you. 7 QUESTIONS BY MR. SNIDOW: 8 Q. All right. You reviewed this 9 study when writing your report? 10 A. I did. This is a meta-analysis 11 that I reviewed, yeah. 12 Q. If we could turn to page 1000. 13 Okay. Do you see it says, "The 14 most consistent pattern of results was 15 observed for the association between prenatal 16 acetaminophen exposure and ADHD symptoms." 17 A. Yes, and I note the symptoms 18 there. 19 Q. Yep. 20 And then it says, "Our findings 21 are consistent with previous single-cohort 22 studies conducted in the ALSPAC, DNBC and 23 INMA cohorts." 24 A. And those also were studies 25 that used ADHD symptoms, yes.</p>

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1 Q. Yeah.

2 You see it says, "The

3 association between prenatal acetaminophen

4 use and ASC symptoms was consistently

5 positive"?

6 A. I do see that.

7 Q. Okay. It says, "Associations

8 between prenatal acetaminophen, ASC and ADHD

9 symptoms were consistently positive for both

10 boys and girls, albeit slightly stronger

11 among boys."

12 Right?

13 A. I see that statement.

14 Q. And so these authors use the

15 term "consistent" one, two, three, four --

16 four times in about three paragraphs?

17 A. That looks to be the case.

18 Q. And you disagree what the

19 author is actually writing this paper, right?

20 A. I disagree with their overall

21 evaluation of the body of evidence because,

22 to my recollection, there's only one study in

23 this meta-analysis that actually had ADHD as

24 a diagnosis. And I think it's very important

25 to think about the difference between results

Page 239

1 on a screening instrument, which are not

2 diagnostic for ADHD, and the ADHD diagnosis

3 itself.

4 There are many, many

5 instruments that were used in this literature

6 that have little to no bearing on the

7 diagnosis of ADHD. And so I disagree with it

8 because of that.

9 Q. Do you think that they're being

10 bad epidemiologists for characterizing the

11 literature as being consistent?

12 MR. MURDICA: Objection to the

13 form.

14 THE WITNESS: I would never

15 call someone a bad epidemiologist.

16 QUESTIONS BY MR. SNIDOW:

17 Q. Okay.

18 A. And I don't -- it's not the

19 point of my disagreeing with their overall

20 results. They can use consistent, if that's

21 how they evaluate their results. That is not

22 informative to my opinion about whether APAP

23 exposure during pregnancy increases the risk

24 of ADHD diagnosis.

25 Q. Well, let me ask you this.

Page 240

1 Let's say a series of results showed ten

2 statistically significant negative results in

3 a row. Okay?

4 .7, all the way down,

5 statistically significant, right?

6 A. Insignificant or significant?

7 Q. Statistically significant.

8 A. .7?

9 Q. Yeah.

10 A. So a protective effect down

11 the -- down the board.

12 Q. Yeah.

13 A. Okay.

14 Q. Do you think it would be

15 unreasonable to characterize that -- those

16 results as consistent in the positive

17 direction?

18 MR. MURDICA: Objection --

19 objection to the form.

20 QUESTIONS BY MR. SNIDOW:

21 Q. Do you want me to draw?

22 A. So in the positive direction,

23 so the result is .7, but you're claiming an

24 increased risk?

25 You don't have to draw it.

Page 241

1 Q. Yeah. That's what I'm saying.

2 A. I think that would be a

3 mischaracterization of the results.

4 Q. I agree.

5 And that's what I'm asking. Is

6 that -- do you think that this is what

7 they're doing here when they say consistent,

8 or is it just a disagreement among

9 epidemiologists about what counts?

10 A. As I said, I don't -- I don't

11 disagree that they are interpreting their

12 results as consistent. It does not inform my

13 opinion as to whether there is a causal

14 association between acetaminophen exposure

15 and ADHD diagnosis because the results that

16 they used in their meta-analysis were based

17 primarily on screening instruments, which are

18 not the same thing as a diagnosis.

19 As you know, screening

20 instruments are designed to cast a wide net.

21 So the sensitivity of those instruments is

22 high in order to capture the risk pool, and

23 that that group of individuals is then

24 further evaluated for diagnosis where we

25 establish a more specific outcome.

Page 242

1 Q. Okay.

2 A. So the two are very different

3 in form.

4 Q. Do you see here they say, "The

5 above-mentioned findings provide biological

6 plausibility"?

7 A. I see that's what they say.

8 Q. Do you think that's a

9 reasonable characterization of the evidence?

10 A. So I want to read the whole

11 sentence. I don't believe that it

12 establishes biological plausibility for a

13 diagnosis of ADHD, which is what I was tasked

14 with doing and what my review consists of.

15 Q. Yeah.

16 A. So, no. Again, picking one

17 sentence out is -- sort of mischaracterizes

18 their overall point. Because if you look at

19 the beginning of the next paragraph, they say

20 we need to interpret these results with

21 caution --

22 Q. Sure.

23 A. -- because these are symptoms

24 and not diagnoses.

25 Q. Okay.

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1 MR. MURDICA: Objection to the

2 form.

3 QUESTIONS BY MR. SNIDOW:

4 Q. Do you agree that the results

5 they describe above provide biological

6 plausibility?

7 A. Not to a diagnosis of ADHD.

8 Q. So you disagree with the study

9 authors again?

10 A. I do.

11 Q. How about coherence? Agree or

12 disagree with the study authors?

13 A. Again, I am looking at this

14 with respect to its influence on my opinion

15 about prenatal APAP exposure and ADHD as an

16 outcome, and I disagree with their

17 characterization of their findings, and it

18 does not inform my opinion.

19 Q. Okay. How about temporality?

20 They say the temporality criterion has been

21 satisfied.

22 Do you agree?

23 A. With respect to their analysis

24 or in general?

25 Q. Uh-huh. With respect to their

Page 244

1 analysis.

2 A. Again, I think they're

3 mischaracterizing the impact of APAP on these

4 screening outcomes and inferring that because

5 they found these effects in screening

6 instruments, it establishes a risk for ADHD

7 as a diagnosis.

8 Q. Well, it's not all screening

9 instruments in this meta-analysis, right?

10 A. There's, I believe, one study.

11 Q. Yeah. Okay.

12 That uses diagnoses, right?

13 A. Yeah.

14 Q. All right. So just to be

15 clear. And then they go on to say

16 dose-response here.

17 And they think that the

18 dose-response criteria in Bradford Hill has

19 been satisfied?

20 A. And I disagree.

21 Q. All right. So you disagree

22 with them -- the study authors themselves

23 on --

24 A. Uh-huh.

25 Q. -- one, two, three, four, five,

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1 what, six of the Bradford Hill criteria?

2 A. I disagree with the summary of

3 the data that these authors have presented --

4 Q. But do you --

5 A. -- in this form, and I think

6 the supplementary tables inform my review and

7 interpretation of this study.

8 Q. But you agree they are doing a

9 Bradford Hill criteria -- Bradford Hill

10 analysis here, right?

11 A. I never --

12 MR. MURDICA: Objection to the

13 form.

14 THE WITNESS: They never state

15 that, but those are the Bradford Hill

16 criteria.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Oh, really? What's footnote

19 42, do you think?

20 A. I'm just saying they don't

21 state it in their paragraph.

22 Q. Well, but they cite to

23 footnote 42.

24 A. Okay. So fine.

25 Q. Do you want to know what that

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1 is?

2 A. I mean, I said it's Bradford

3 Hill criteria.

4 Q. Yeah. That's the Bradford Hill

5 address? Yeah.

6 So in that paragraph, they're

7 doing the Bradford Hill analysis, right?

8 A. They're doing a Bradford Hill

9 analysis on data that is not complete --

10 Q. Okay.

11 A. -- because they have not

12 included what the supplementary tables

13 include.

14 Q. Okay.

15 A. And they are coming up with a

16 summary of the findings based on incomplete

17 presentation of the data.

18 Q. And that's fine.

19 MR. MURDICA: J.J., I'm going

20 to ask you again nicely. I'm sure

21 it's unintentional, but you keep doing

22 it. You can't help yourself, and just

23 please try.

24 QUESTIONS BY MR. SNIDOW:

25 Q. They say one, two, three, four,

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1 five -- six of the Bradford Hill criteria are

2 satisfied?

3 A. I thought we just went through

4 this, but that's what they say.

5 Q. Yeah. Okay. Thank you. You

6 can put that one aside.

7 (Pinto-Martin Exhibit 613

8 marked for identification.)

9 QUESTIONS BY MR. SNIDOW:

10 Q. All right. Can I have L?

11 Are you familiar with the

12 Briggs textbook?

13 A. I've seen it referred to in

14 some of the expert reports. It's not a

15 textbook I've ever looked at. It's not -- I

16 would have no reason to. I'm not an

17 obstetrician.

18 Q. Oh, is that what it's for?

19 It's for obstetricians?

20 A. I believe so.

21 Q. All right. It says, "A

22 Reference Guide to Fetal and Neonatal Risk."

23 Right?

24 A. My understanding is it's for

25 clinicians, but, again, I've never seen it,

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1 so...

2 Q. All right. So this is designed

3 for doctors who are dealing with pregnant

4 women?

5 MR. MURDICA: Objection to the

6 form.

7 THE WITNESS: I don't know what

8 it was designed for. I wasn't part of

9 its publication, but my understanding

10 is that it's a reference for

11 clinicians.

12 QUESTIONS BY MR. SNIDOW:

13 Q. And you see it's in its 12th

14 edition?

15 A. I see that.

16 Q. So, yes, it's been around for a

17 bit; is that right?

18 A. I would imagine. I don't know

19 when the first publication was, but, yes, I

20 would imagine it's been around for at least

21 12 years.

22 Q. All right. I'm going to mark

23 it as 613.

24 A. Oh, boy, this one I really need

25 my --

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1 Q. Yeah.

2 A. These give me a headache,

3 that's the problem.

4 Yeah. That's really hard to

5 read.

6 Q. You see here you've got a

7 section on acetaminophen, right?

8 A. Uh-huh. Can this -- can this

9 enlarge this little thing?

10 Q. Yeah.

11 A. That would be great, because

12 this is really hard to read.

13 Q. Yeah, yeah, yeah.

14 MR. MURDICA: It's blurry on

15 here too. I'm not sure that it's

16 going to help it.

17 THE WITNESS: I think his copy

18 is -- well --

19 QUESTIONS BY MR. SNIDOW:

20 Q. Is that better?

21 A. Did I mess it up?

22 Q. Good?

23 A. Does anyone know how this

24 works? Oh, it's got to go -- we've got it.

25 Thank you.

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1 Yeah, that's better. It's
 2 easier to read.
 3 Do you want to look at this
 4 one, too? If you want --
 5 Q. Are you ready?
 6 A. Yeah.
 7 Q. It says, "Acetaminophen is
 8 commonly used in all stages of pregnancy."
 9 Right?
 10 A. That's what it says.
 11 Q. It says, "Although originally
 12 thought not to cause embryo-fetal harm, this
 13 assessment must change because of recent
 14 data."
 15 Correct?
 16 MR. MURDICA: Objection to the
 17 form.
 18 THE WITNESS: There's what it
 19 says.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. And then it calls out ADHD in
 22 particular?
 23 A. Although the risk is very low,
 24 use of the drug for seven -- several weeks or
 25 longer has been associated with -- (reading

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1 sotto voce).
 2 It does. It does.
 3 Q. And do you agree with the study
 4 authors?
 5 A. As I've said, I do not believe
 6 there's credible epidemiologic evidence to
 7 support an increased risk of ADHD from
 8 prenatal APAP use.
 9 Q. So you think that the Briggs
 10 textbook authors are wrong to be telling
 11 obstetricians that the assessment of APAP
 12 must change because of recent data?
 13 A. I don't know anything about the
 14 Briggs textbook. I don't know who the
 15 authors are. I don't really know who the
 16 audience is, although I think it is
 17 clinicians, and I don't know what data they
 18 evaluated.
 19 I don't know when this was
 20 written and why they decided to put this in
 21 there, so I really can't comment. It's not
 22 my area of expertise. I'm not willing to
 23 opine on why that's in there.
 24 Q. Okay. You say you don't -- you
 25 don't make causal determinations on the basis

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1 of observational data; is that right?
 2 A. That's right.
 3 Q. All right. Do you make causal
 4 determinations on the basis of randomized
 5 controlled trials?
 6 A. I don't know that I've ever
 7 made a causal determination on the basis of
 8 an RCT. I have been involved with some RCTs.
 9 They certainly rule out many of the problems
 10 of confounding and bias that a observational
 11 study contains.
 12 So I would say I would be more
 13 likely to accept evidence from an RCT than I
 14 would from an observational study with
 15 respect to establishing a causal association.
 16 Q. Well, isn't that how the FDA
 17 determined whether drugs work, because they
 18 do RCT?
 19 MR. MURDICA: Objection to the
 20 form.
 21 THE WITNESS: I'm have no idea
 22 hat the FDA does. I'm not an FDA
 23 employee. I don't know what kinds of
 24 studies they do or how they evaluate
 25 their evidence.

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. You really don't know before
 3 approving a drug the FDA requires a
 4 randomized control trial?
 5 MR. MURDICA: Objection to
 6 form.
 7 THE WITNESS: I know that there
 8 are a series of steps you have to go
 9 through to approve a drug, but it's
 10 not something that I've ever studied
 11 or know about.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Okay. Do you think that an RCT
 14 would pretty definitively answer the question
 15 of whether acetaminophen use in utero causes
 16 autism?
 17 A. Well, it's a hypothetical
 18 that's impossible to do, so I've never really
 19 given it consideration. You can't randomly
 20 assign women to receive a medication that at
 21 this point has some suggestion of harm.
 22 Q. Right.
 23 Yeah. So that's kind of what I
 24 was getting at. You think it would be
 25 unethical, right?

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1 MR. MURDICA: Objection to the
2 form.
3 THE WITNESS: We do not allow
4 randomized clinical trials, except at
5 the moment of what we call equipoise,
6 where there is not sufficient evidence
7 on one side or the other.
8 It's very hard to establish
9 that point in time, and I think we're
10 past that now because there are
11 studies suggesting a risk.
12 And so, first of all, which --
13 what women would enroll in a study
14 like that? And it would be unethical.
15 QUESTIONS BY MR. SNIDOW:
16 Q. And suggesting the risk of
17 what?
18 MR. MURDICA: Objection to the
19 form.
20 THE WITNESS: I'm sorry? I
21 just lost you there.
22 QUESTIONS BY MR. SNIDOW:
23 Q. You said there are -- you can't
24 do it at this point because there's studies
25 suggesting the risk. Suggesting the risk of

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1 what?
2 A. So there's studies that report
3 an elevated risk of ASD, ADHD and some
4 findings on screening instruments that are
5 very flawed but nonetheless have been
6 published and have been picked up by the
7 media.
8 And so that information is out
9 there, and the public has digested it and --
10 Q. And because of that, you can't
11 do a clinical trial anymore, right?
12 MR. MURDICA: Objection to the
13 form.
14 THE WITNESS: Because of that
15 and because in general we don't allow
16 pregnant women to enroll in clinical
17 trials because of the vulnerability of
18 the fetus.
19 QUESTIONS BY MR. SNIDOW:
20 Q. Right.
21 But put just the general
22 pregnancy point aside. You actually don't
23 think that there's a causal association
24 between APAP and autism or ADHD, right?
25 A. That's correct.

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1 Q. And you're 100 percent certain
2 of that, right?
3 A. As I said, I am certain based
4 on the body of literature that I've reviewed
5 that no evidence for a causal association
6 exists for ASD or ADHD.
7 Q. That's a little different,
8 though.
9 Are you certain that it doesn't
10 cause it?
11 A. As I said, all I can be certain
12 on is what I've reviewed and evaluated, and
13 I've reviewed and evaluated the studies, and
14 my conclusion on the basis of that review and
15 evaluation is that there's not credible
16 evidence of a causal association for either
17 of those outcomes.
18 Q. So why would it be unethical to
19 do the RCT?
20 MR. MURDICA: Objection to the
21 form.
22 THE WITNESS: It's unethical to
23 do RCTs in pregnant women.
24 QUESTIONS BY MR. SNIDOW:
25 Q. Put that one aside.

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1 A. I can't put that one aside.
2 It's --
3 Q. It's not the one you told me
4 first. You said it would be unethical
5 because of what we know now on risk.
6 MR. MURDICA: And objection to
7 the form. And you -- please stop.
8 You really got to stop interrupting
9 the witness.
10 QUESTIONS BY MR. SNIDOW:
11 Q. Go ahead.
12 Why -- why would the risk of
13 APAP, which you think is entirely the result
14 of confounding and bias -- why would that
15 preclude you from doing an RCT on ethical
16 grounds?
17 MR. MURDICA: Objection to the
18 form.
19 THE WITNESS: So I think it
20 would be unethical to ask a woman to
21 enroll in a study where she has heard
22 on media or law websites that this
23 substance might put her baby at risk.
24 I think just the suggestion of
25 an association is enough to make a

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1 woman worry, and I think it would be
 2 unethical to subject a woman to that
 3 kind of -- of worry and anxiety. So
 4 it's unethical from that reason.
 5 **QUESTIONS BY MR. SNIDOW:**
 6 Q. Can you point me to any
 7 publication or authority that says it's
 8 unethical to do a clinical trial based on
 9 what's been reported in the press rather than
 10 the science?
 11 MR. MURDICA: Objection to the
 12 form.
 13 THE WITNESS: I can point to a
 14 textbook definition of equipoise,
 15 which I think speaks to this exact
 16 issue, that a clinical trial can be
 17 launched when we are at a point where
 18 nobody really knows anything about the
 19 risk, and you can legitimately enroll
 20 people and expose them to something
 21 because we have no evidence to suggest
 22 that that exposure might increase the
 23 risk.
 24 And as I've said, there are
 25 reported elevated risk estimates from

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1 these studies that have been captured
 2 and publicized, and so we are not at
 3 the moment of equipoise.
 4 **QUESTIONS BY MR. SNIDOW:**
 5 Q. We're not at the moment of
 6 equipoise?
 7 A. We are not at the moment of
 8 equipoise.
 9 MR. SNIDOW: Okay. Jim, can we
 10 take a quick break?
 11 MR. MURDICA: We're taking
 12 lunch in eight minutes.
 13 MR. SNIDOW: Okay. Perfect.
 14 **QUESTIONS BY MR. SNIDOW:**
 15 Q. All right. Can you go to
 16 page 36 of your report?
 17 A. Yes.
 18 Q. And there you report a set of
 19 results for autism and prenatal APAP use?
 20 A. Correct.
 21 Q. You chose these again?
 22 A. I did.
 23 Q. And you report, I think you
 24 say, five of them?
 25 A. That's right.

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1 Q. All right.
 2 A. Yeah.
 3 Q. Yeah.
 4 A. Liew, Ji, Ji, Hornig and
 5 Saunders.
 6 Q. Okay. And you told me before
 7 that Liew 2016 is the strongest, the best?
 8 A. So Liew 2016 is based on the
 9 largest sample with, I would say, the most
 10 accurate, although very imperfect, measure of
 11 exposure. So among this group, I would
 12 describe it as the methodologically
 13 strongest.
 14 Q. Yeah. Remember you said -- I
 15 asked what are the better-designed studies,
 16 you said Liew 2016, right?
 17 A. As I said, among the five
 18 studies, I think this one has strengths over
 19 the others. It still has many problems, but
 20 it has strengths over the others.
 21 Q. Okay. So the result for ASD
 22 there was 1.19?
 23 A. That's correct. The overall
 24 result for ASD was 1.19.
 25 Q. And that's statistically

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1 significant?
 2 A. It is in the report, yes.
 3 Q. All right. And you said in
 4 your report the better-designed studies don't
 5 show an association, right?
 6 MR. MURDICA: Objection to the
 7 form.
 8 **QUESTIONS BY MR. SNIDOW:**
 9 Q. On page 5. Remember that?
 10 A. I'm reminding myself of my
 11 exact phrase, but, yes, that does sound
 12 familiar.
 13 Q. Okay. And Liew, that's the
 14 better-designed study you're referring to?
 15 A. Among the five that report on
 16 ASD outcome, this one is based on the
 17 best-designed study, yes.
 18 Q. Okay. And would you mind
 19 looking at the table real quick and just
 20 telling me if my forest plot here -- if you
 21 see any obvious errors?
 22 MR. MURDICA: Objection to the
 23 form and the use of this
 24 demonstrative.
 25 MR. SNIDOW: In most

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1 litigations, you guys like the forest
2 plot.
3 THE WITNESS: It looks to be an
4 accurate representation of what I had
5 in the table.
6 QUESTIONS BY MR. SNIDOW:
7 Q. Okay. All right. Do you agree
8 that all the results except for this one here
9 have a point estimate above 1.0?
10 A. That is what is reported by the
11 authors. That is what is reflected in your
12 forest plot here. And again, it is one
13 measure of -- one aspect of my interpretation
14 of these data, and I have to always
15 characterize it in the context of the
16 underlying data on exposure, which is
17 exceedingly weak.
18 So a point estimate that's
19 above 1 based on data that I think is highly
20 flawed is not the same thing as a point
21 estimate of above 1 on data that is solid and
22 reliable and valid.
23 Q. Yeah, and I get it. I just --
24 just to be clear, though, for what that
25 means, the point estimate above 1 means in

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1 all these studies except for this subgroup,
2 the woman who was exposed to APAP, or in this
3 case more APAP, had a higher rate of having a
4 child with ASD, right?
5 MR. MURDICA: Objection to the
6 form.
7 THE WITNESS: That is what the
8 study authors have reported. However,
9 I don't think that that's a fair
10 characterization of the data because
11 the underlying exposure information is
12 so flimsy that it doesn't hold up in
13 my mind in terms of characterizing an
14 increased risk.
15 QUESTIONS BY MR. SNIDOW:
16 Q. Okay. But it's an accurate
17 representation of the results, right?
18 A. The point results -- the point
19 estimates are above 1 and statistically
20 significant, and those have to be evaluated
21 in the context of the -- of the quality of
22 the underlying data.
23 MR. MURDICA: Objection to the
24 form.
25 MR. SNIDOW: All right.

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1 Lunchtime?
2 MR. MURDICA: Sure.
3 VIDEOGRAPHER: The time is
4 12:19 p.m., and we are off the record.
5 (Off the record at 12:19 p.m.)
6 VIDEOGRAPHER: The time is
7 12:54 p.m., and we're on the record.
8 QUESTIONS BY MR. SNIDOW:
9 Q. Okay. Dr. Pinto-Martin, when
10 you were on break, did you -- did you find
11 that study you were telling me about where it
12 showed that pre or post-pregnancy use was
13 associated with an autism diagnosis in the
14 child?
15 MR. MURDICA: Objection to
16 form.
17 You know we just had a break
18 for lunch. That's what
19 Dr. Pinto-Martin did, was she ate
20 lunch.
21 QUESTIONS BY MR. SNIDOW:
22 Q. Okay. So sorry, did you find
23 that article?
24 A. I didn't have time. I barely
25 had time -- I didn't even time to finish my

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1 lunch.
2 So I'm sorry, I did not have
3 time to do that.
4 Q. Would you mind looking on the
5 next break?
6 MR. MURDICA: Objection to
7 form.
8 Just stop asking. Okay? You
9 don't get to tell the witness what to
10 do.
11 MR. SNIDOW: Well, here's the
12 thing. Here's the thing. I don't
13 think it exists, and I really want to
14 be sure of that.
15 MR. MURDICA: We don't care
16 about your opinion. Just ask
17 questions.
18 QUESTIONS BY MR. SNIDOW:
19 Q. So will you next time -- I'm
20 going to ask you every break, because it's
21 not fair. Okay?
22 You've got to tell me if these
23 exist or don't exist, so I want you to
24 look --
25 MR. MURDICA: Please conduct

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1 yourself appropriately, Mr. Snidow.
 2 That's not --
 3 QUESTIONS BY MR. SNIDOW:
 4 Q. Okay. Could -- I'm going to
 5 show you this demonstrative.
 6 Do you remember the secondhand
 7 smoke data we were looking at?
 8 A. I remember that, yes.
 9 Q. And you remember the risk
 10 ratios were all between about -- well, a
 11 little bit negative and a maximum of 1.3 or
 12 so?
 13 A. Are we talking about the
 14 sibling -- I mean, the spouse or the child?
 15 Q. Actually, all of them.
 16 A. Okay.
 17 Q. Sure.
 18 A. Yeah, I would like to refresh,
 19 but, yes, that sounds about right.
 20 Q. All right. And I'm not saying
 21 exactly, but this is approximately what that
 22 association looks like; that you get a third
 23 more than in the no secondhand smoke one?
 24 MR. MURDICA: Object to the
 25 form and the use of the demonstrative

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1 you created.
 2 THE WITNESS: I mean, I think
 3 we have the point estimates in the
 4 report, so I don't know why we need to
 5 see a graphic demonstration of it. I
 6 don't -- I don't really feel like that
 7 adds anything, but --
 8 QUESTIONS BY MR. SNIDOW:
 9 Q. Yeah. I'm just -- is it an
 10 accurate graphic demonstration, though?
 11 This is what a risk ratio of
 12 1.3 in the secondhand smoke literature,
 13 that's what it looks like.
 14 A. I mean, if you were -- yeah --
 15 MR. MURDICA: Objection to the
 16 form.
 17 THE WITNESS: Again, it just
 18 seems a strange way to take an actual,
 19 established risk. This is more of a
 20 teaching method to show how we might
 21 derive it, but it's not wrong.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Okay. Thank you.
 24 Has there ever been a
 25 randomized controlled trial on the

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1 relationship between active smoking and lung
 2 cancer?
 3 A. I do not believe that a
 4 randomized controlled trial would have ever
 5 been authorized because of ethical
 6 considerations.
 7 Q. So it wasn't an equipoise,
 8 right? At least after the '50s or so?
 9 A. Right. As soon as we had
 10 established that there was potential for
 11 increased risk, we are beyond the point of
 12 equipoise.
 13 Q. Yeah.
 14 Do you agree that in the middle
 15 of the 20th century, '50s or so, there were
 16 many epidemiologists who argued that the
 17 relationship between smoking and lung cancer
 18 was due to confounding?
 19 A. I was not reviewing
 20 epidemiology studies on smoking and lung
 21 cancer in the '50s.
 22 Q. Uh-huh.
 23 A. I was a child. So I can't
 24 really respond to that.
 25 Q. Okay. Do you agree, though,

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1 it's always theoretically possible to say
 2 that a result might be due to unmeasured
 3 confounding?
 4 MR. MURDICA: Objection to
 5 form.
 6 THE WITNESS: Do I agree that
 7 it's always theoretically possible?
 8 I mean, unmeasured confounding
 9 is a fact of life in observational
 10 studies, and we always assess for the
 11 risk of that in our analytic
 12 strategies. Or at least I do, and I
 13 think most reasonable epidemiologists
 14 do.
 15 So I think that's how I would
 16 describe it, is when you're doing your
 17 analysis, you look at the putative
 18 confounders and assess for them if you
 19 have data on them.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. Right.
 22 That's what I'm saying. It's
 23 always possible that you missed something.
 24 MR. MURDICA: Objection to
 25 form.

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. Right?
 3 A. It's always possible that you
 4 missed something. I mean, that's a very
 5 general statement.
 6 Q. Okay. Do you remember this?
 7 A. I remember this, yeah.
 8 Q. No matter how good your study
 9 is, it's always possible that there's some
 10 confounder out there that's actually driving
 11 the results.
 12 Is that true?
 13 MR. MURDICA: Objection to
 14 form.
 15 THE WITNESS: Absolutely true.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. Absolutely true. Okay.
 18 And same thing for residual
 19 confounding, right? Even if you've
 20 controlled for something explicitly, it's
 21 possible that your data sucked, right?
 22 MR. MURDICA: Objection to
 23 form.
 24 THE WITNESS: That's one
 25 interpretation.

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. And in that situation, it's
 3 theoretically possible that there's residual
 4 confounding?
 5 A. Residual confounding is always
 6 a possibility.
 7 Q. And that's my question.
 8 No matter how good your study
 9 is, best study in the world, outside of the
 10 RCT context, there's always going to be the
 11 possibility for residual and unmeasured
 12 confounding, right?
 13 A. Which is why I talk about the
 14 challenges of observational studies.
 15 Q. No, I agree.
 16 A. Epidemiology.
 17 Q. Do you agree with me, though,
 18 always possible, every study, no matter how
 19 good?
 20 MR. MURDICA: Objection to
 21 form.
 22 THE WITNESS: That's a very
 23 firm, broad statement. I don't know.
 24 Maybe there's -- maybe there is a
 25 perfect observational study that could

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1 be designed that was free of bias and
 2 confounding. I haven't seen it, but I
 3 couldn't say that it would never be
 4 possible.
 5 QUESTIONS BY MR. SNIDOW:
 6 Q. Have you ever seen one like
 7 that?
 8 A. I've never seen one.
 9 Q. No.
 10 Is that a no, you've never seen
 11 one like that?
 12 MR. MURDICA: Objection to
 13 form.
 14 THE WITNESS: I've never seen a
 15 study like that, but I'm saying --
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. Sure.
 18 A. Maybe someone could do it.
 19 MR. MURDICA: You're doing it
 20 again. You just did "okay" and "sure"
 21 there, and I know you're saying it's
 22 not intentional, I don't think it is,
 23 but if there's any way to stop it,
 24 it's very distracting, and it
 25 interrupts the witness.

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1 (Pinto-Martin Exhibit 617
 2 marked for identification.)
 3 QUESTIONS BY MR. SNIDOW:
 4 Q. I'm going to show you a
 5 document that I'm marking 617.
 6 MR. MURDICA: Well, are you
 7 going to acknowledge that you're going
 8 to try to fix that or not?
 9 MR. SNIDOW: No, I'm not.
 10 MR. WATTS: Don't talk to him.
 11 Keep asking questions. Come on.
 12 MR. SNIDOW: Here's one for
 13 you.
 14 Let's just move on. Let's just
 15 move on.
 16 MR. MURDICA: You keep talking
 17 in the middle of her answers.
 18 MR. SNIDOW: Ladies, please,
 19 you're both pretty. Let's move on.
 20 Okay?
 21 MR. MURDICA: I don't even know
 22 what that means. That seems wildly
 23 inappropriate to say to a female
 24 witness. I don't know --
 25 MR. SNIDOW: I wasn't --

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1 MR. MURDICA: -- what your
2 problem is --
3 THE WITNESS: I'm really
4 offended by that.
5 MR. SNIDOW: I wasn't talking
6 to the witness.
7 THE WITNESS: I'm sure you
8 weren't, but it's still an offensive
9 comment, so --
10 MR. SNIDOW: I was talking to
11 Mr. Watts.
12 MR. MURDICA: You need --
13 THE WITNESS: It's still an
14 offensive comment, so --
15 MR. MURDICA: You need to get
16 it under control real quick.
17 MR. SNIDOW: Okay.
18 THE WITNESS: I find that
19 offensive.
20 QUESTIONS BY MR. SNIDOW:
21 Q. You see this Smoking and Health
22 from the Surgeon General?
23 A. I do.
24 Q. This is the report that was
25 used to establish likelihood of causation for

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1 tobacco?
2 MR. MURDICA: Objection to the
3 form.
4 THE WITNESS: I don't know how
5 this report was used, but if I have a
6 chance to read it, I can look to see
7 who called for it and to whom it went
8 and what was done with the data.
9 But I don't know looking at it
10 right now.
11 QUESTIONS BY MR. SNIDOW:
12 Q. You really haven't seen the
13 Surgeon General report on smoking and health?
14 MR. MURDICA: Objection to the
15 form.
16 THE WITNESS: I have not read
17 this report.
18 QUESTIONS BY MR. SNIDOW:
19 Q. Okay. Well, let's look at
20 page 593.
21 Oh, I'm sorry, 190.
22 A. Okay.
23 Q. All right. Do you see where it
24 says "Constitutional hypothesis"?
25 A. I do.

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1 Q. And it says, "Thus far in the
2 evaluation, the committee has considered
3 whether the available data are consistent
4 with the hypothesis that smoking causes
5 cancer of the lung."
6 Do you see that?
7 A. That is the first sentence of
8 that paragraph.
9 Q. Then it says, "The analysis
10 must consider with equal attention the
11 alternative hypothesis that both the smoking
12 of cigarettes and cancer of the lung have a
13 common cause which determines both that an
14 individual shall become a smoker and also
15 that he shall be predisposed to lung cancer."
16 Right?
17 A. That's correct.
18 Q. And that's describing
19 confounding, right?
20 A. That's describing confounding.
21 Q. And what that's suggesting is,
22 oh, well, maybe there's something out there
23 that's associated both with smoking and with
24 lung cancer, and we just haven't found it
25 yet.

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1 Right?
2 A. That is what that's suggesting,
3 I would agree.
4 Q. And that argument is, though,
5 the one you're making here, right; that
6 there's a confounder, mainly genetics and
7 indication, that's associated both with
8 prenatal APAP use and autism.
9 True?
10 MR. MURDICA: Objection to the
11 form.
12 THE WITNESS: So the
13 difference, I would say, is that I
14 think we have evidence that both
15 genetics and indication of use act as
16 potential confounders in that
17 relationship.
18 QUESTIONS BY MR. SNIDOW:
19 Q. Yeah. I'm obviously not saying
20 they were right. I'm just saying the form of
21 the argument is the same one that you're
22 making, right?
23 A. Uh-huh.
24 Q. Yeah.
25 And, actually, it's a little

<p style="text-align: right;">Page 278</p> <p>1 more specific, because if you look down a 2 little bit farther down the page, it says, 3 "Fisher has been foremost in calling 4 attention to the possibility that cancer of 5 the lung and the habit of smoking may be due 6 to a common genotype." 7 Is that right? 8 A. I see that sentence. 9 Q. Do you know who Ronald Fisher 10 was? 11 A. I imagine -- 12 MR. MURDICA: Objection to the 13 form. 14 THE WITNESS: -- it's Fisher, 15 the statistician, but I have no idea 16 based on this. 17 QUESTIONS BY MR. SNIDOW: 18 Q. It is. 19 And who is Fisher, the 20 statistician? 21 A. He is a famous statistician who 22 developed the Fisher's exact test. 23 Q. Yes. 24 And the F-test is named for 25 him?</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. Okay. That's a pretty good 2 contribution to the literature, don't you 3 think? 4 MR. MURDICA: Objection to 5 form. 6 THE WITNESS: I agree. He's an 7 important statistician. 8 QUESTIONS BY MR. SNIDOW: 9 Q. And he said that "The habit of 10 smoking may be due to a common genotype with 11 lung cancer," right? 12 A. That's what that says. 13 Q. "Selection of smokers then 14 would automatically provide a population in 15 which pulmonary cancer would appear on the 16 basis of" -- "basis of genetic 17 susceptibility." 18 Right? 19 A. That's a hypothesis that he's 20 putting forth, if that confounder is there. 21 Q. And that is, if I understand 22 correctly, exactly the same argument that 23 you're making with respect to prenatal APAP 24 use, autism and ADHD, right? 25 MR. MURDICA: Objection to</p>
<p style="text-align: right;">Page 279</p> <p>1 A. I believe that's correct. 2 Q. The Student t-test that he 3 was -- he developed it or helped to? 4 A. I don't know exactly what he 5 did or didn't do, but I know that he's a 6 statistician that is often cited. 7 Q. But possibly the most important 8 statistician of the 20th century; is that 9 right? 10 MR. MURDICA: Objection to 11 form. 12 THE WITNESS: I can't 13 characterize him that way. I know 14 that I studied his textbook when I was 15 in graduate school. 16 QUESTIONS BY MR. SNIDOW: 17 Q. He came up with the concept of 18 the null hypothesis? 19 MR. MURDICA: Objection. Form. 20 THE WITNESS: I believe that's 21 true. 22 QUESTIONS BY MR. SNIDOW: 23 Q. You said you believe that's 24 true? 25 A. Uh-huh.</p>	<p style="text-align: right;">Page 281</p> <p>1 form. 2 THE WITNESS: Again, I'm trying 3 to get a sense, you know, of the 4 whole -- of the whole argument here 5 because just pulling the one line out 6 is a little hard for me to react to. 7 QUESTIONS BY MR. SNIDOW: 8 Q. Yeah, go ahead and read. 9 A. Okay. I think I -- I think 10 that his illustration of the potential role 11 of genetic confounding is similar to what I'm 12 arguing in my example here. 13 Q. Yeah. 14 A. Well, your example here because 15 I made it generic, and you've now made it 16 specific to APAP and autism. 17 Q. Yeah, that was okay. 18 Right? 19 MR. MURDICA: Objection to 20 form. 21 QUESTIONS BY MR. SNIDOW: 22 Q. Did you mind that I made the 23 confounding diagram? 24 MR. MURDICA: Objection to 25 form.</p>

<p style="text-align: right;">Page 282</p> <p>1 THE WITNESS: I think it's</p> <p>2 irrelevant whether I find it --</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. Well, sorry. It does describe</p> <p>5 what you think is going on here, right?</p> <p>6 MR. MURDICA: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: It does describe</p> <p>9 what I have proposed.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. All right. And let's look at</p> <p>12 what evidence Fisher relied on for his</p> <p>13 genetic confounding theory.</p> <p>14 He points to studies on</p> <p>15 monozygotic pairs of twins; is that right?</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: He does point to</p> <p>19 the difference between monozygotic</p> <p>20 twin pairs and dizygotic twin pairs in</p> <p>21 terms of smoking.</p> <p>22 QUESTIONS BY MR. SNIDOW:</p> <p>23 Q. And that is exactly the same</p> <p>24 kind of evidence that you point to to show</p> <p>25 that autism is genetic, right?</p>	<p style="text-align: right;">Page 284</p> <p>1 not understanding the whole context. I'd</p> <p>2 sort of like to take a minute and read the</p> <p>3 whole couple of paragraphs and maybe a couple</p> <p>4 of pages to understand exactly what his</p> <p>5 argument is and what the flow of his argument</p> <p>6 might be.</p> <p>7 Q. Okay.</p> <p>8 A. Because you're taking one</p> <p>9 sentence at a time, and it's hard to react to</p> <p>10 them --</p> <p>11 MR. MURDICA: You can. You're</p> <p>12 allowed --</p> <p>13 THE WITNESS: -- in isolation.</p> <p>14 MR. MURDICA: You're allowed</p> <p>15 to.</p> <p>16 THE WITNESS: Yeah.</p> <p>17 QUESTIONS BY MR. SNIDOW:</p> <p>18 Q. Yeah. You can look.</p> <p>19 A. I'll do it this way.</p> <p>20 Okay.</p> <p>21 Q. All right. Are you ready?</p> <p>22 A. Well, I can stop --</p> <p>23 MR. MURDICA: You let him --</p> <p>24 you can tell him when you're ready.</p> <p>25 You take as much time as you need.</p>
<p style="text-align: right;">Page 283</p> <p>1 MR. MURDICA: Objection to the</p> <p>2 form.</p> <p>3 THE WITNESS: The basis of the</p> <p>4 heritability estimate for autism is</p> <p>5 the concordance rate for monozygotic</p> <p>6 twins and dizygotic twins, yes.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. And that's Fisher's statement</p> <p>9 for saying that it might be genetic</p> <p>10 confounding in smoking and lung cancer; is</p> <p>11 that true?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: I believe that</p> <p>15 that's what he's saying in this</p> <p>16 paragraph, not having read the entire</p> <p>17 report, pulling that out.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. He goes on to say that "The</p> <p>20 data on smoking habits of identical and</p> <p>21 fraternal twins raised apart are compatible</p> <p>22 with that hypothesis."</p> <p>23 Do you see that?</p> <p>24 A. Again, this is very hard for me</p> <p>25 to do, to be reading sentence by sentence and</p>	<p style="text-align: right;">Page 285</p> <p>1 THE WITNESS: I mean, I can</p> <p>2 read -- read on.</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. No.</p> <p>5 MR. MURDICA: Well --</p> <p>6 THE WITNESS: Because it's</p> <p>7 all -- I don't know what you're going</p> <p>8 to ask me about.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Right. So let me --</p> <p>11 A. But I'd like to understand the</p> <p>12 whole --</p> <p>13 Q. So let me -- let me try to walk</p> <p>14 you through it.</p> <p>15 Richard {sic} Fisher also</p> <p>16 pointed out that cigarette smokers were</p> <p>17 different in certain ways than people who</p> <p>18 didn't smoke cigarettes.</p> <p>19 Right? Did you see that there?</p> <p>20 A. He does talk about the</p> <p>21 differences, yes.</p> <p>22 Q. And you think that women who</p> <p>23 take APAP while pregnant are different than</p> <p>24 women who do not take APAP in certain ways,</p> <p>25 right?</p>

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1 MR. MURDICA: Objection. Form.
 2 THE WITNESS: I think there's
 3 evidence to suggest that women who
 4 take APAP during pregnancy are more
 5 prone to depression and to anxiety and
 6 to comorbid symptomatology that means
 7 that they're willing to continue to
 8 take medication during pregnancy or
 9 they need to continue to take
 10 medication during pregnancy.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Including neuroticism.
 13 Is that right?
 14 MR. MURDICA: Objection. Form.
 15 THE WITNESS: What do you mean
 16 "including neuroticism"?
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. Do you think that women who
 19 take APAP are more likely to be neurotic than
 20 women who don't?
 21 A. So there is a study that
 22 evaluated the trait of neuroticism and
 23 supports the idea that women who have more
 24 neurotic traits are more likely to take APAP
 25 during pregnancy.

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1 Q. If we look up here, it says,
 2 "Cigarette smokers have been described as
 3 consuming more alcohol, drinking more, being
 4 more neurotic, engaging more often in
 5 athletics and being more likely to have at
 6 least one parent with hypertension or
 7 coronary disease."
 8 Right?
 9 A. Okay. So now you're jumping up
 10 to a paragraph that I haven't even looked at
 11 yet, so --
 12 Q. Right. Take a look. Take a
 13 look.
 14 A. Can -- can I just --
 15 Q. I had said you can have as long
 16 as you like. So take a look.
 17 A. Okay. I want to read the whole
 18 thing. Genetic considerations.
 19 When was this written? It's
 20 sort of making me laugh because some of the
 21 terms that are used.
 22 Q. Yeah, no. It is -- it is
 23 dated.
 24 A. Masculinity.
 25 Q. Yeah. That's -- they thought

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1 that might have been one of the confounders,
 2 too.
 3 A. Uh-huh.
 4 Q. Hold on, and I'll tell you.
 5 1964.
 6 A. Okay. Okay. I mean, I think
 7 I've got the flavor of it.
 8 Q. Okay. You got -- you got the
 9 gist of it?
 10 A. Yeah.
 11 Q. All right. He's suggesting
 12 that there's confounding because cigarette
 13 smokers are different in certain ways than
 14 non-cigarette smokers, right?
 15 A. Uh-huh.
 16 Q. And some of the ways are the
 17 same ones that you point to here, right,
 18 alcohol?
 19 A. Uh-huh.
 20 Q. Neuroticism?
 21 A. Again, there's a study that
 22 suggests that, yeah.
 23 Q. And family history, right?
 24 A. Right, which would be, I guess,
 25 genetics --

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1 Q. Yeah.
 2 A. -- as explained through family
 3 history, yeah.
 4 Q. Okay. And just to be clear,
 5 you think that this was very wrong for him to
 6 suggest at the time, right?
 7 MR. MURDICA: Objection. Form.
 8 THE WITNESS: I never said that
 9 I thought it was very wrong for him to
 10 suggest at the time. I didn't know he
 11 suggested it at the time. I'm reading
 12 this for the first time.
 13 QUESTIONS BY MR. SNIDOW:
 14 Q. Okay. Do you think that was
 15 wrong of him to suggest at the time?
 16 A. No. I don't think it was wrong
 17 of him to suggest at the time. It was a
 18 hypothesis that was put forth to test with
 19 data.
 20 Q. Yeah.
 21 So you think it was fine for
 22 Fisher in 1964 to suggest that maybe the
 23 relationship between smoking and lung cancer
 24 was the result of confounding?
 25 MR. MURDICA: Objection to

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1 form.

2 THE WITNESS: I'm sorry, can

3 you repeat the question?

4 QUESTIONS BY MR. SNIDOW:

5 Q. Yeah.

6 You think it was fine for

7 Fisher in 1964 to suggest that the

8 relationship between smoking and lung cancer

9 was possibly due to confounding?

10 MR. MURDICA: Objection to

11 form.

12 THE WITNESS: I think it was a

13 reasonable hypothesis that he was

14 putting forth to see if it could be

15 tested.

16 QUESTIONS BY MR. SNIDOW:

17 Q. Okay. Do you know what the

18 risk ratios for smoking and lung cancer are?

19 MR. MURDICA: Objection to

20 form.

21 THE WITNESS: Not off the top

22 of my head, but I imagine they're

23 quite high.

24 QUESTIONS BY MR. SNIDOW:

25 Q. Double digits?

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1 MR. MURDICA: Objection to

2 form.

3 THE WITNESS: Again, I don't

4 know without looking at a specific

5 study.

6 QUESTIONS BY MR. SNIDOW:

7 Q. Okay. Do you think it's --

8 well, never mind. That's fine.

9 Are you aware that one of the

10 pieces of evidence that the Surgeon General

11 considered pretty compelling was the fact

12 that lung cancer and cigarettes had gone up

13 in the same fashion over the decades

14 preceding the 1960s?

15 MR. MURDICA: Objection to

16 form.

17 You can answer.

18 THE WITNESS: I have no idea

19 what the Surgeon General considered in

20 terms of the overall evidence. That

21 is ecological evidence.

22 And as we know, ecological

23 evidence is very easily explained by

24 other factors, and that's certainly

25 true in the acetaminophen and

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1 neurodevelopmental disorder story as

2 well.

3 QUESTIONS BY MR. SNIDOW:

4 Q. Can you look at page 179 of

5 this?

6 You see direct measure of the

7 association?

8 A. Uh-huh.

9 Q. Do you see that there were

10 seven prospective studies at this time on

11 smoking and lung cancer?

12 A. "Seven prospective studies

13 consider the occurrence or lack of occurrence

14 of lung cancer among smokers and nonsmokers."

15 Yes, I see that.

16 Q. Do you think that's a

17 consistent association?

18 MR. MURDICA: Objection to

19 form.

20 THE WITNESS: Again, I don't

21 have the studies in front of me. If I

22 had time to review them and look at

23 the data behind those -- behind that

24 statement, I'd be happy to give an

25 opinion.

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Okay. Do you see here it says,

3 "Others believe that the lung cancer rise is

4 spurious and can be attributed either to

5 improvements in diagnosis and reporting"?

6 A. I do see that statement.

7 Q. Okay. And --

8 MR. MURDICA: You didn't read

9 it all in there.

10 MR. SNIDOW: Oh, I'm sorry.

11 MR. MURDICA: You didn't

12 complete the sentence.

13 QUESTIONS BY MR. SNIDOW:

14 Q. "Or to the aging of the

15 population."

16 Do you see that?

17 A. I see that statement, yes.

18 Q. And so what the -- what the

19 smoker skeptics here are suggesting is that

20 there's a difference between the prevalence

21 and the incidence rate for lung cancer,

22 right?

23 MR. MURDICA: Objection to

24 form.

25 THE WITNESS: Again, I think

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1 you're inferring something that they
2 are not stating here, but I understand
3 why you say that. You know,
4 prevalence and incidence are
5 different, as we talked about before.
6 QUESTIONS BY MR. SNIDOW:
7 Q. Well, they're saying the lung
8 cancer rise is spurious, true?
9 MR. MURDICA: Objection to
10 form.
11 THE WITNESS: They're saying
12 that some believe that the lung cancer
13 rise is spurious and might be a
14 diagnostic reporting issue,
15 ascertainment issue.
16 QUESTIONS BY MR. SNIDOW:
17 Q. Yeah.
18 And that's what you think is
19 going on here with autism?
20 MR. MURDICA: Objection to
21 form.
22 THE WITNESS: So I think that
23 the data supporting the increased
24 prevalence of autism, which I am very
25 familiar with because I was part of

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1 the team that has been collecting that
2 data for the CDC, uses a methodology
3 that relies on medical records alone.
4 There's no in-person evaluation of
5 children.
6 We've been doing it now for
7 about ten years or more. And the
8 methodology is, I would say now,
9 somewhat biased by the fact that we
10 continue to do it.
11 And I'd be happy to talk about
12 the specifics of that bias, but I
13 believe there is some perhaps
14 overascertainment or overcalling of
15 the presence.
16 That being said, that's only
17 one reason why the prevalence might be
18 increasing over time. We know that
19 the diagnostic criteria has changed,
20 and at least prior to the most recent
21 change to DSM-5, the umbrella was
22 larger, and it was easier to be
23 labeled with autism spectrum disorder
24 than it had been in the past.
25 Furthermore, the awareness of

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1 autism and the likelihood of early
2 detection has been dramatically
3 changed over the past 10 to 15 years
4 because of public awareness.
5 So all of those things are
6 going to contribute to an inflated
7 prevalence estimate, and none of them
8 address the issue of whether there's
9 actually an increased incidence.
10 QUESTIONS BY MR. SNIDOW:
11 Q. So is that a, yeah, you think
12 that the rise in autism is a spurious -- a
13 spurious one?
14 MR. MURDICA: Objection to
15 form.
16 THE WITNESS: I'm not saying
17 that the -- I'm saying that there are
18 methodologic reasons that contribute
19 to the increased prevalence, and we
20 need to acknowledge those and not
21 assume that it's due to an actual
22 increase in the risk of acquiring the
23 disease --
24 QUESTIONS BY MR. SNIDOW:
25 Q. Okay.

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1 A. -- which would be the
2 incidence.
3 Q. Can you go to 27 for a second?
4 A. (Witness complies.)
5 Q. Actually, I'll do it with a
6 different statement. Okay.
7 (Pinto-Martin Exhibit 614
8 marked for identification.)
9 QUESTIONS BY MR. SNIDOW:
10 Q. I'm going to show you an
11 exhibit I'm going to mark as GGG, and that
12 will be -- thanks -- mark as 614.
13 A. Thank you.
14 Q. Okay. Do you see this is a
15 letter to the editor in Nature in 1958?
16 A. I do.
17 Q. Nature is a pretty good
18 journal, right?
19 MR. MURDICA: Objection to the
20 form.
21 THE WITNESS: I have no idea
22 what Nature in 1958 was like.
23 QUESTIONS BY MR. SNIDOW:
24 Q. Okay. Pretty good journal
25 today?

<p style="text-align: right;">Page 298</p> <p>1 A. Nature -- Nature today has a 2 good reputation. 3 Q. And do you see this is from 4 Ronald Fisher? 5 A. Sure enough. 6 Q. Part of genetics at Cambridge, 7 right? 8 A. Uh-huh. 9 Q. And he's talking about cancer 10 and smoking, right? 11 A. Uh-huh. 12 Q. And he says, "Such results 13 suggest that an error has been made of an old 14 kind in arguing from correlation to 15 causation," right? 16 A. I'm sorry, I've lost where you 17 are. 18 MR. MURDICA: Where are you? 19 QUESTIONS BY MR. SNIDOW: 20 Q. Second paragraph. 21 A. Such results -- okay. Again, 22 I'd like to read this whole thing. I'm 23 fascinated by this actually, being a historic 24 epidemiologist. 25 But can I read the whole thing?</p>	<p style="text-align: right;">Page 300</p> <p>1 think -- you think the plaintiff experts are 2 making here, right? 3 MR. MURDICA: Objection to the 4 form. 5 THE WITNESS: So I would say 6 that's an oversimplification of the 7 error that I believe has been made. I 8 think it's certainly part of it, 9 but... 10 QUESTIONS BY MR. SNIDOW: 11 Q. Okay. Then he repeats his 12 genetic confounding argument, right? 13 A. Uh-huh. 14 Q. Then he goes on to say, 15 "Unfortunately, considerable propaganda is 16 now being developed to convince the public 17 that cigarette smoking is dangerous." 18 Right? 19 A. That's what he says. 20 Q. And you agree that that 21 propaganda which he said was dangerous to the 22 public ultimately turned out to be 23 100 percent correct, right? 24 MR. MURDICA: Objection to the 25 form.</p>
<p style="text-align: right;">Page 299</p> <p>1 Q. Uh-huh. 2 A. Okay. 3 MR. MURDICA: I think I showed 4 up to the wrong deposition. I was 5 planning to do one on acetaminophen, 6 and we're -- 7 THE WITNESS: Curious relation. 8 MR. MURDICA: -- it's on 9 smoking. 10 THE WITNESS: This is great. 11 I'm going to use it in my teaching. 12 It's good. 13 He was a good writer. You got 14 to give him that. 15 QUESTIONS BY MR. SNIDOW: 16 Q. Uh-huh. 17 A. This is great. 18 Okay. 19 Q. I'm glad you think so. 20 Okay. You see where it says, 21 "Such results suggest that an error has been 22 made of an old kind arguing from correlation 23 to causation"? 24 A. I do. 25 Q. And that's the error that you</p>	<p style="text-align: right;">Page 301</p> <p>1 THE WITNESS: So I believe that 2 that was a statement that he made at 3 the time that he believed was true, 4 and I believe later the evidence 5 was counter -- ran counter to that. 6 QUESTIONS BY MR. SNIDOW: 7 Q. And do you think that the 8 people who were promoting evidence in favor 9 of the link between tobacco and cigarette 10 smoking were wrong to promote it, even before 11 the link was 100 percent definitive? 12 MR. MURDICA: Objection to 13 form. 14 THE WITNESS: That's a hard 15 question to answer because I don't 16 know what the weight of the evidence 17 back was when people were putting 18 forth their belief that it was 19 dangerous. 20 So it's really sort of 21 impossible for me to say whether it 22 was right or wrong. I imagine they 23 were doing it with the best intention, 24 but I really have no way of knowing. 25 It was a long time ago.</p>

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Well, I'm talking about the

3 ones who are saying that tobacco does cause

4 lung cancer. Those guys were definitely

5 right to promote that view, right?

6 MR. MURDICA: Objection to

7 form.

8 THE WITNESS: Again, without

9 knowledge of what the state of the

10 evidence was at the time that they

11 were promote -- promoting that view, I

12 would not be willing to comment.

13 QUESTIONS BY MR. SNIDOW:

14 Q. Okay. So you can't give me a

15 clean answer on whether the people in the

16 1950s and early 1960s who said, "Yes, tobacco

17 does cause lung cancer," whether they were

18 right to promote that view?

19 MR. MURDICA: Objection to

20 form.

21 THE WITNESS: Again, I was not

22 around to see the data that was being

23 relied upon to make statements about

24 that, so I would not be willing to

25 give an opinion on whether they were

Page 303

1 right or wrong.

2 QUESTIONS BY MR. SNIDOW:

3 Q. Isn't it generally considered

4 the biggest achievement in epidemiology what

5 they did?

6 MR. MURDICA: Objection to

7 form.

8 THE WITNESS: I don't have an

9 opinion on that. I've never --

10 QUESTIONS BY MR. SNIDOW:

11 Q. You don't -- well --

12 MR. MURDICA: Well, she was

13 talking and you interrupted her again.

14 MR. SNIDOW: I didn't mean to.

15 QUESTIONS BY MR. SNIDOW:

16 Q. You said you don't have an

17 opinion on that.

18 Go ahead.

19 A. I don't think in terms of the

20 greatest achievement. I think in terms of

21 careful science and diligent search for the

22 truth, which I think was done in this

23 instance and has been done in other

24 instances.

25 Q. Okay. You can put that aside

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1 now.

2 Do you agree that for a

3 variable to be a confounder, it needs to be a

4 true cause of the outcome of interest?

5 A. I think I've -- I think that

6 the true cause is what's giving me hesitation

7 here.

8 Q. Yeah.

9 A. Because something can confound

10 an association by a -- an overall association

11 by, I would say, reducing the overall impact

12 of the measure of association.

13 So I think it can have an

14 impact without being the cause.

15 Q. And are you saying that there

16 can be partial confounding?

17 A. Correct.

18 Q. That's what you're saying.

19 Okay.

20 But even the partial

21 confounding, the confounding agent needs to

22 actually cause the outcome, right?

23 A. It needs to have an

24 established, reliable, valid association with

25 the outcome. Again, the cause concern -- the

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1 word "cause" concerns me because we will

2 evaluate a confounder without knowing whether

3 it's causal -- causally related. But if we

4 see a reduction, we say it's a confounder.

5 Q. But isn't that just in an

6 abundance of caution?

7 Like, in other words, you cast

8 your net a little broader than the ones you

9 think are actual cause just in case, right?

10 A. We cast a wide net if we have

11 data on the potential confounders, we examine

12 them, and we look to see what that does to

13 the measure of association.

14 Q. Do you have Exhibit 605 in

15 front of you?

16 A. If I can find it.

17 Q. And while you're doing that,

18 let me give you an example I think will clear

19 it up.

20 MR. MURDICA: Well, hang on.

21 You can ask her to do one thing. You

22 can't ask her a question while she's

23 trying to --

24 MR. SNIDOW: She's just getting

25 it.

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1 THE WITNESS: Okay. This is
 2 the --
 3 MR. SNIDOW: 605?
 4 THE WITNESS: -- Federal
 5 Judicial Center thing?
 6 QUESTIONS BY MR. SNIDOW:
 7 Q. Yeah. Just hold on for a
 8 second.
 9 So I don't know what your
 10 favorite example of confounding is. Mine is
 11 gray hair color and mortality.
 12 Is that a good one?
 13 A. That's a pretty basic one,
 14 yeah.
 15 MR. WATTS: I object.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. And the -- no hair.
 18 And the confounder is, of
 19 course, age, right?
 20 A. Correct.
 21 Q. Right.
 22 And so if you were doing a
 23 study on, let's say, smoking and mortality,
 24 you wouldn't need to control for gray hair,
 25 right?

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1 MR. MURDICA: Objection. Form.
 2 THE WITNESS: Gray hair is a
 3 proxy for age, so --
 4 QUESTIONS BY MR. SNIDOW:
 5 Q. Right.
 6 A. -- you would need to control
 7 for it in its true form.
 8 Q. You need to control for age,
 9 right?
 10 A. Right.
 11 Q. If you control for age, you
 12 wouldn't also need to control for gray hair?
 13 A. But should you control for gray
 14 hair, you would see a difference in the
 15 effect estimate, and then you would need to
 16 identify what that meant.
 17 And that was my earlier point,
 18 that something can be suspected to be a
 19 confounder and can later be revealed that
 20 it's not that, it's associated with something
 21 else that the -- that is the actual
 22 confounder.
 23 Q. Yeah. I was actually going to
 24 ask you that, too.
 25 If you can't control for

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1 something directly, you can control for a
 2 correlate.
 3 A. If you know what the correlate
 4 is, and you have data on that correlate --
 5 Q. Yeah.
 6 A. -- that's reliable and valid,
 7 you can enter that into the model to see if
 8 it makes a difference.
 9 Q. So in other words, let's say I
 10 couldn't control for age in my study.
 11 A. Yep.
 12 Q. They just lost the data. But I
 13 had data on hair gray, it's not going to be a
 14 perfect measure of age, but it's still better
 15 than nothing, right?
 16 MR. MURDICA: Objection to
 17 form.
 18 THE WITNESS: It's a proxy for
 19 age, so...
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. And that's one way of
 22 controlling for confounders that you can't
 23 see, is by controlling for proxies?
 24 MR. MURDICA: Objection to
 25 form.

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1 THE WITNESS: I would agree
 2 that there are times when we don't
 3 have the exact data that we would like
 4 to enter into the model to see if it
 5 makes a difference, and we may use a
 6 proxy for that.
 7 I think we need to understand
 8 how it might be approximately
 9 associated with the confounder we're
 10 thinking about, but, yes, I will grant
 11 you that.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. And one way you can control for
 14 confounders is using multiple regression
 15 models?
 16 A. Correct.
 17 Q. Another way you can control for
 18 confounders is by doing stratifications?
 19 A. Correct.
 20 Q. And just to walk through with
 21 our example, if I did -- if I did gray
 22 hair -- if I did, let's say, smoking and
 23 mortality and, you know, there was some age
 24 confounder, I could control for age, and then
 25 whether the association went away or not

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1 would determine whether there was actual
 2 confounding effect, right?
 3 MR. MURDICA: Objection to
 4 form.
 5 THE WITNESS: So I believe
 6 you're saying you would stratify on
 7 age and see if the effect estimate was
 8 the same in those two strata?
 9 QUESTIONS BY MR. SNIDOW:
 10 Q. Yeah.
 11 A. That is one approach, yes.
 12 Q. Okay. And then for
 13 multivariate regression, let's say -- what
 14 did I say, gray hair, mortality. And
 15 obviously we think the confounder is age.
 16 The other thing I could do is I
 17 could just make a very long multivariate
 18 model that included age and see whether the
 19 association between gray hair and mortality
 20 stayed the same, right?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: I'm not really
 24 following you because you told me that
 25 gray hair -- you didn't have

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1 information on age.
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. No. No. Forget that one.
 4 A. You said you'd use gray hair as
 5 a proxy.
 6 MR. MURDICA: You can't wave
 7 your hand and talk in the middle of
 8 her answer. You keep doing it.
 9 Please, please. I'm asking you very
 10 kindly to stop.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Let's say I did a regression of
 13 gray hair and mortality.
 14 All right?
 15 A. Okay.
 16 Q. I would get an association.
 17 A. Okay.
 18 Q. Definitely spurious, right?
 19 A. Okay.
 20 Q. The way to test that, one way,
 21 would be to do a multivariate analysis and
 22 include age in my model.
 23 A. Okay. I'm following you in
 24 that.
 25 Q. Is that right?

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1 A. But you would -- before you did
 2 that, you would first look at the correlation
 3 between gray hair and age and see that they
 4 were very strongly correlated, and you might
 5 not enter them both into your model because
 6 that's not the way we do it.
 7 But fair enough.
 8 Q. Yep.
 9 And my question was if we had
 10 my model and including age made the
 11 association go away, that would be good
 12 evidence that the association between gray
 13 hair and mortality was confounded, right?
 14 MR. MURDICA: Objection to
 15 form.
 16 THE WITNESS: If you added age
 17 to the model and your association with
 18 gray hair went away, you -- if you
 19 knew the correlation between gray hair
 20 and age, you could say that is serving
 21 as a proxy for age and it's no longer
 22 significant in the face of age, which
 23 is actually the variable that's
 24 driving the association.
 25

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. Yep.
 3 And similarly, if you control
 4 for something and the association doesn't
 5 change, that's good evidence that it's not
 6 confounding, right?
 7 MR. MURDICA: Object to form.
 8 THE WITNESS: I think that's a
 9 little trickier because it depends on
 10 the reliability and validity of the
 11 data for that confounder.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Yeah.
 14 A. So it could be that it doesn't
 15 change because it's an imperfect measure of
 16 the confounder. It could be that it doesn't
 17 change because the confounder is actually
 18 tied to something else that you haven't
 19 measured.
 20 So I think it's a little easier
 21 to agree with the first and a little harder
 22 to agree with the second.
 23 Q. But assume I had measured
 24 perfectly, perfect measurement of everything,
 25 I know it's not --

<p>Page 314</p> <p>1 A. I mean, theoretically.</p> <p>2 Q. Yeah. Theoretically, a perfect</p> <p>3 measure for everything, if you control for</p> <p>4 something and the association doesn't change,</p> <p>5 that's evidence that whatever you're putting</p> <p>6 in the model is not a confounder?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Yeah. And, you</p> <p>10 know, this is -- this is so</p> <p>11 theoretical, and it's so unlikely,</p> <p>12 that it's hard to -- you know, it's</p> <p>13 hard to disagree with you, but it's</p> <p>14 also hard to agree with you because</p> <p>15 it's not -- it's not reality based.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. Well, that is why you do</p> <p>18 multivariate regression, right?</p> <p>19 MR. MURDICA: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: Again, it's why</p> <p>22 you do multivariate regression --</p> <p>23 regression with good data. And here,</p> <p>24 you're talking about something that's</p> <p>25 completely hypothetical and</p>	<p>Page 316</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Can you tell me any particular</p> <p>3 one? What specifically did they fail to</p> <p>4 control for across all of the studies, or</p> <p>5 any, if you want?</p> <p>6 MR. MURDICA: Same objection.</p> <p>7 THE WITNESS: I can't answer</p> <p>8 across all because, as I said, there</p> <p>9 are differences among the studies.</p> <p>10 I'll give you an example.</p> <p>11 The Ji study, which used the --</p> <p>12 Ji studies, which used the Boston</p> <p>13 Birth Cohort as a basis for their</p> <p>14 analysis, did not control for genetic</p> <p>15 confounding. And that's a very</p> <p>16 significant confounder and a very</p> <p>17 significant limitation, among others,</p> <p>18 of the results that they present.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. All right. Besides genetics,</p> <p>21 anything else?</p> <p>22 A. So there are studies that,</p> <p>23 although they attempted to control for</p> <p>24 confounding by indication, based that control</p> <p>25 on very imprecise and imperfect maternal</p>
<p>Page 315</p> <p>1 impossible.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Okay. Let's put genetics aside</p> <p>4 for a moment.</p> <p>5 What causal risk factors do you</p> <p>6 think have not been controlled for in any of</p> <p>7 the studies looking at the relationship</p> <p>8 between prenatal APAP exposure and ASD?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: So I'd have to go</p> <p>12 through the studies and look at the</p> <p>13 specific list of confounders. You</p> <p>14 know, each cohort study included a</p> <p>15 different set. I would tell you that</p> <p>16 none of them included all of the most</p> <p>17 important confounders that I would</p> <p>18 consider.</p> <p>19 So I can't, off the top of my</p> <p>20 head, say MoBa didn't control for</p> <p>21 this, DNBC did, you know. I think I</p> <p>22 would have to look at it.</p> <p>23 But I would say that none of</p> <p>24 them controlled for everything that</p> <p>25 might be relevant in that association.</p>	<p>Page 317</p> <p>1 report of indications, and often that</p> <p>2 indication is not tied to the actual exposure</p> <p>3 of acetaminophen.</p> <p>4 So an imperfect control for</p> <p>5 something that is a very important,</p> <p>6 underlying, methodologic challenge.</p> <p>7 Q. All right. Anything else?</p> <p>8 A. Those are the two big ones in</p> <p>9 my mind. As I've said before, genetics and</p> <p>10 confounding by indication are the two that I</p> <p>11 would say are front of mind when I'm</p> <p>12 reviewing these studies.</p> <p>13 Q. So aside from those two,</p> <p>14 sitting here right now, you can't think of</p> <p>15 any causal confounder that was not controlled</p> <p>16 for across the studies?</p> <p>17 MR. MURDICA: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: Again, I would</p> <p>20 want to review the studies, review the</p> <p>21 confounders they considered, and give</p> <p>22 it the proper consideration before I</p> <p>23 answered that, you know,</p> <p>24 categorically.</p> <p>25 But as I said, the two most</p>

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1 important confounders were not
2 thoroughly controlled in many of the
3 studies.
4 QUESTIONS BY MR. SNIDOW:
5 Q. And sitting here right now, you
6 can't think of any others?
7 MR. MURDICA: Object to form.
8 THE WITNESS: I've tried to
9 answer that question. I said I'm
10 unwilling to, you know, use memory and
11 try to recall which ones were included
12 and not included. I would want to
13 review the studies and review the
14 specifics of the confounders they
15 collected, and the -- and the
16 integrity of that data.
17 QUESTIONS BY MR. SNIDOW:
18 Q. Okay. You know that many of
19 the study authors have said that confounding
20 by indication is unlikely, right?
21 MR. MURDICA: Objection to
22 form.
23 THE WITNESS: I would like to
24 have you point to a specific citation.
25 I've certainly seen that, but I

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1 don't -- are we done with this one, by
2 the way? Because I pulled it out and
3 we don't need it.
4 I don't necessarily agree with
5 that characterization.
6 QUESTIONS BY MR. SNIDOW:
7 Q. Well, I'm pulling out a study
8 now, but while they're doing that, I'm not
9 asking whether you agree.
10 You know that a lot of the
11 study authors have said, we've looked at the
12 data; we don't think confounding by
13 indication is very likely?
14 MR. MURDICA: Objection to
15 form.
16 THE WITNESS: Again, I know
17 that study authors have said that.
18 And as I've just explained, the data
19 on confounding by indication in many
20 cases is imperfect at best. And so in
21 my mind, it's overstepping the data to
22 make a conclusion like that.
23 (Pinto-Martin Exhibit 615
24 marked for identification.)
25

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1 QUESTIONS BY MR. SNIDOW:
2 Q. Okay. So here's Ricci 2023,
3 which I'll mark as 615.
4 A. Another meta-analysis?
5 Q. Yeah. Yes.
6 All right. And it sounds like
7 you're familiar with this because you knew it
8 was a meta-analysis, right?
9 A. I did.
10 Q. All right. And they say that
11 "The objective of the study was to assess the
12 extent to which the association is due to
13 confounding by indication."
14 Right?
15 A. Correct.
16 Q. And that is one of the two
17 things that you think is confounding this
18 relationship; the other being genetics,
19 right?
20 A. Uh-huh.
21 MR. MURDICA: Objection to
22 form.
23 THE WITNESS: I agree.
24 QUESTIONS BY MR. SNIDOW:
25 Q. You agree.

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1 All right. So that's the
2 objective of their study.
3 And then if we go to the
4 conclusion of their study, they say,
5 "Confounding by indication did not explain
6 the association between in utero
7 acetaminophen exposure and child ADHD."
8 Right?
9 A. So that is the box that's been
10 pulled out on the second page of the article.
11 And as often is the case, it's an
12 oversimplified view of their final results.
13 Q. Okay. Hold on. Let's look at
14 the final results then.
15 Let's go -- let's go to 9,
16 Principal Findings.
17 And this isn't in the abstract
18 anymore, right?
19 A. Correct.
20 Q. Okay. So it says here,
21 "Principal findings are findings indicating a
22 small to moderate association between in
23 utero acetaminophen exposure and risk of
24 child ADHD, which did not appear to be
25 explained by confounding by indication."

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1 Did I read that correctly?

2 A. You did, and I think their

3 language is important which did not appear to

4 be explained by confounding by indication.

5 Q. Well, let's --

6 A. Can we turn to their

7 conclusions?

8 Q. Let's first look at their

9 chart.

10 So at the top, they actually do

11 a forest plot, right?

12 A. They do.

13 Q. And they say that this forest

14 plot is adjusted for maternal and infant

15 characteristics and confounding by

16 indication.

17 Right?

18 A. So they are relying on a set of

19 studies that attempted to control for

20 confounding by indication, and as I've said

21 before, the data that they're relying on is

22 imperfect.

23 We do not have a direct -- a

24 direct piece of evidence on the indication

25 for acetaminophen use and the timing of

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1 exposure relevant to that indication.

2 Q. Yeah.

3 A. And so they are using a set of

4 data that's imperfect with respect to this

5 potential confounder. They analyzed it

6 anyway, and they were unable to demonstrate

7 that it had an impact.

8 And in their conclusions, they

9 state as much. So in their conclusions, I

10 just want to point out --

11 Q. Yeah.

12 A. -- that they say, "However, the

13 certainty of the evidence on this topic is

14 low, and findings should be interpreted in

15 light of the limitations of the existing

16 studies," -- what I was just referring to --

17 "as well as the limited number of

18 sufficiently comparable studies available to

19 meta analyze. These findings strongly

20 suggest the need for high-quality studies

21 with adequate control for both measured and

22 unmeasured maternal indications for

23 acetaminophen use."

24 So they're saying we didn't

25 have that, and that's what we need.

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1 MR. MURDICA: You talked three

2 times during her answer there. You've

3 got to try to stop. You did.

4 QUESTIONS BY MR. SNIDOW:

5 Q. Would you mind going to page 9?

6 MR. MURDICA: You're on video

7 doing it. I'm trying to help you

8 here.

9 QUESTIONS BY MR. SNIDOW:

10 Q. Do you mind going to page 9

11 that we were just looking at?

12 A. Yeah, I see it.

13 Q. My question was just going to

14 be -- what I asked was, in their -- I know

15 you think it was imperfectly done, but what

16 they're saying is they produced this

17 meta-analysis adjusting for confounding by

18 indication, right?

19 That's what they say. I know

20 you disagree, but that's what they say?

21 MR. MURDICA: Object to form.

22 THE WITNESS: Again, you're

23 taking one line here, and they say

24 that, and then they qualify it in

25 their conclusions, which I would argue

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1 is one of the most important sections

2 of any epidemiologic study.

3 Why? Because an honest

4 epidemiologist will acknowledge, I did

5 my best, and there are these problems

6 that must be considered in order to

7 evaluate the credibility of this

8 evidence with respect to a causal --

9 hypothesized causal association.

10 QUESTIONS BY MR. SNIDOW:

11 Q. All right. Let me ask it a

12 different way.

13 Did the Ricci meta-analysis

14 conclude that there was confounding by

15 indication that could explain this

16 association?

17 A. Again, their pooled estimate

18 does not support confounding by indication.

19 Q. Okay.

20 A. And yet they state that that

21 data is imperfect and needs to be followed up

22 with more precise and accurate data.

23 Q. That's all I wanted.

24 All right. Do you have the

25 Alemany study in front of you?

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1 A. Remind me what number it was,
 2 if you remember. I can find it, I'm sure.
 3 Did you give it to me?
 4 MS. BARRIERE: Try 612.
 5 THE WITNESS: So mine goes from
 6 611 to 613, so something happened to
 7 Alemany along the way. Let's see if
 8 it got misfiled.
 9 Oh, here we go. I got it. It
 10 was just out of order.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. All right. Can you turn to
 13 page 1001?
 14 A. (Witness complies.)
 15 Q. Are you there?
 16 A. 1001.
 17 Q. You see where it says
 18 "however"?
 19 A. Uh-huh.
 20 Q. It says, "However, the
 21 consistent associations found across
 22 different sensitivity analysis, including
 23 examining ASC and ADHD diagnosis in the
 24 largest cohort, makes unlikely that the
 25 observed relationship between prenatal

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1 acetaminophen and ASC and ADHD symptoms is
 2 entirely explained by unmeasured
 3 confounding."
 4 Did I read that correctly?
 5 A. That is their statement.
 6 Q. And do you disagree with these
 7 study authors too?
 8 A. I do.
 9 Q. You do?
 10 A. I do.
 11 Q. Okay. Have you -- have you
 12 written to them to tell them that they're
 13 very wrong on that?
 14 MR. MURDICA: Objection to
 15 form.
 16 THE WITNESS: I have not
 17 written any letters directly to
 18 authors, which I actually have never
 19 done, and I've not written a letter to
 20 the editor, which I have done in the
 21 past, because as I said, the past
 22 period of time, that has not been my
 23 focus.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. But you do -- you do disagree

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1 with these authors?
 2 A. I do.
 3 Q. Can I have H, which we've done?
 4 Do you have Olsen and Liew in
 5 front of you? 609?
 6 Do you have it?
 7 A. I have it.
 8 Q. All right. Turn to page 1395.
 9 A. What is it -- oh, it's the
 10 first page. Okay.
 11 Q. Uh-huh.
 12 Do you see where it says
 13 "Several analytical methods"?
 14 A. Uh-huh.
 15 Q. It says, "Several analytical
 16 methods that aim to minimize confounding bias
 17 have been utilized in these studies."
 18 Right?
 19 A. That's what it says.
 20 Q. And then it describes a
 21 propensity score match method?
 22 A. Uh-huh.
 23 Q. Sibling-controlled analysis?
 24 A. Uh-huh.
 25 Q. And negative control

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1 comparison?
 2 A. Uh-huh.
 3 Q. And it says they've all given
 4 consistent results, right?
 5 A. That's what it says. I
 6 disagree with that statement.
 7 Q. All right. Hold on.
 8 And it says, "Providing
 9 additional evidence against confounding as
 10 the primary reason to explain away the
 11 possible fetal programming of acetaminophen
 12 on brain function in childhood."
 13 Did I read that correctly?
 14 A. You read it correctly, but I --
 15 Q. Do you disagree with these
 16 study authors, too?
 17 A. I do.
 18 Q. Have you written to them?
 19 MR. MURDICA: Objection to
 20 form.
 21 You asked these same questions
 22 before the break.
 23 THE WITNESS: As I said, I --
 24 I've never written to a study author,
 25 and I have not written to the editor

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1 to describe my feelings about the
2 study.
3 Again, I'm not ruling out that
4 it's something that I might not do in
5 the future. I have not done it to
6 date.
7 MR. SNIDOW: And you're right,
8 Jim. I forgot I did.
9 (Pinto-Martin Exhibit 618
10 marked for identification.)
11 QUESTIONS BY MR. SNIDOW:
12 Q. All right. I'm going to show
13 you Bauer and Kriebel, which I will mark --
14 MR. SNIDOW: What are we up to,
15 Christy {sic}?
16 COURT REPORTER: I don't know
17 because I think one of them got marked
18 out of order.
19 MR. SNIDOW: Okay.
20 COURT REPORTER: So I don't
21 want to tell you one --
22 THE WITNESS: I have 617 as my
23 last one.
24 MR. CHARCHALIS: You marked
25 Surgeon General report as 617, and

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1 then you went back and you marked --
2 you marked the Nature in 1958 as 14 --
3 MR. SNIDOW: Uh-huh. Can I
4 do --
5 MR. CHARCHALIS: -- and then
6 you marked Ricci as 15, and you didn't
7 do 16.
8 QUESTIONS BY MR. SNIDOW:
9 Q. Okay. This one is going to be
10 18.
11 A. Okay. So we're missing 16?
12 Q. Yeah.
13 A. That's why I was confused.
14 Q. All right. Do you see the
15 Bauer and Kriebel article?
16 A. I do.
17 Q. If we go to page 134, do you
18 see where it says "Together these nine
19 studies"?
20 A. Ah, sorry, I'm not there yet.
21 Okay. "Together these nine studies."
22 Q. Okay. "Together these nine
23 studies and five cohorts provide a strong
24 body of evidence suggesting
25 neurodevelopmental effects of prenatal APAP

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1 exposure."
2 Did I read that correctly?
3 A. You did.
4 Q. And then two sentences later it
5 says, "Several lines of reasoning suggest
6 that bias, confounding and chance are not
7 solely responsible for the observed
8 relationships."
9 Did I read that correctly?
10 A. You did.
11 Q. And I know you -- you probably
12 disagree with the study authors on that
13 point, right?
14 MR. MURDICA: Objection to
15 form.
16 THE WITNESS: So I agree -- I
17 disagree with the study authors'
18 review of the evidence with respect to
19 its support of a causal association
20 between acetaminophen and ASD or ADHD.
21 QUESTIONS BY MR. SNIDOW:
22 Q. Do you think this sentence is
23 unreasonable, "several lines of reasoning
24 suggest that bias, confounding and chance are
25 not solely responsible"?

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1 A. Again, I'm not going to comment
2 on the reasonableness or unreasonableness of
3 a statement that is made in the middle of a
4 review article. You know my opinion on the
5 evidence and its support of a causal
6 association.
7 And so I, therefore, agree
8 with -- I disagree, sorry, with the
9 authors --
10 Q. Okay.
11 A. -- and the conclusions.
12 Q. All right. Then they say
13 there's evidence of a dose-response gradient,
14 right?
15 A. I see that.
16 Q. And do you agree that there's
17 evidence of dose-response in this literature?
18 A. I do not agree there's evidence
19 of a dose-response. As I've mentioned
20 before, I think the fragility of the dosing
21 information where we have no information on
22 actual dose, on actual timing of dose and
23 duration of dose, renders it really virtually
24 impossible to conduct a valid dose-response
25 relationship.

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1 Nevertheless, many authors have
 2 tried to do it.
 3 Q. Yeah.
 4 You see where it says, "No
 5 associations were found with ibuprofen or
 6 other analgesic medications suggested
 7 specificity of the association with APAP"?
 8 A. I do see that.
 9 Q. And you know that there were
 10 studies that looked for a link between
 11 ibuprofen and neurodevelopmental outcomes?
 12 A. I do know that, and
 13 importantly, we have to recognize that women
 14 are advised against taking ibuprofen during
 15 pregnancy, so they will substitute ibuprofen
 16 with, for example, another analgesic like
 17 acetaminophen.
 18 And, therefore, the numbers who
 19 report ibuprofen use are very small, so we
 20 might have the problem of inadequate power to
 21 test the association.
 22 In addition, the -- the dose of
 23 ibuprofen is even weaker than the dose and
 24 duration information that we have on
 25 acetaminophen. It's often characterized as a

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1 dichotomous yes or no.
 2 Q. All right. Any studies that do
 3 show a link between ibuprofen use and autism?
 4 A. Again --
 5 MR. MURDICA: Objection to
 6 form.
 7 THE WITNESS: -- as I said, the
 8 data is very thin and weak because
 9 women are just -- are advised not to
 10 take it, and so we have very few
 11 studies that even asked about it, and
 12 where they did, it was a yes/no.
 13 So in my mind, that's not
 14 adequate to rule that out as a
 15 potential.
 16 MR. MURDICA: When you're --
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. I'm just asking, is there a
 19 study that showed a link between ibuprofen
 20 and autism? Can you name me that study?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: There is not a
 24 study. That was not my point.
 25

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. Sorry. That's all I wanted.
 3 And same answer for ADHD?
 4 MR. MURDICA: Objection to
 5 form.
 6 THE WITNESS: The same issue
 7 arises with respect to ADHD, which is
 8 that women are advised not to take
 9 ibuprofen during pregnancy. Very few
 10 of them do, and we still have the
 11 problem with recall bias, and we have
 12 the problem with a yes/no measurement
 13 of exposure.
 14 MR. MURDICA: We've been going
 15 an hour. When you're done --
 16 MR. SNIDOW: Yep.
 17 MR. MURDICA: -- with the line
 18 of questioning, if you want to take a
 19 break, we'd be good with that.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. So can you name me a study that
 22 showed a link between prenatal APAP use and
 23 ADHD?
 24 MR. MURDICA: Objection to
 25 form.

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1 THE WITNESS: As I just said,
 2 that data is weak, and we do not have
 3 a study showing that.
 4 MR. SNIDOW: Okay. Yeah. We
 5 can go off the record.
 6 VIDEOGRAPHER: The time is
 7 1:54 p.m., and we are off the record.
 8 (Off the record at 1:54 p.m.)
 9 VIDEOGRAPHER: The time is
 10 2:07 p.m., and we are on the record.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. Okay. Dr. Pinto-Martin, have
 13 you found the studies showing a pre or
 14 post-pregnancy use of APAP is associated with
 15 the autism diagnosis?
 16 MR. MURDICA: Objection to
 17 form.
 18 You know she hasn't because she
 19 hasn't had a chance. If you want her
 20 to look on record, just tell her to
 21 look now.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Have you -- were you able to
 24 look?
 25 A. I believe that the question was

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1 just answered. I have not had time to look.
 2 Q. Okay. You know, we're going to
 3 do this right now. Will you please look for
 4 me?
 5 And I'll -- you know, you can
 6 take the time you like, but realize what I'm
 7 asking is prenatal APAP use, pre-prenatal
 8 APAP use and autism diagnosis, post-pregnancy
 9 use and autism diagnosis. Take a look at
 10 your report.
 11 A. So you're asking me about a
 12 negative control exposure analysis that had
 13 autism as the outcome?
 14 Q. Correct.
 15 A. Okay. I will look in my
 16 report.
 17 Q. Yeah.
 18 A. So in reviewing my report,
 19 there is not a study that looks specifically
 20 at pre or post-pregnancy use and --
 21 Q. For autism?
 22 A. Autism. The studies that do
 23 that analysis have both autism and ADHD as an
 24 outcome, but their analysis was restricted to
 25 pre or post-pregnancy use and ADHD.

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1 Q. Okay. So no evidence that pre
 2 or post-pregnancy use of acetaminophen is
 3 associated with autism?
 4 MR. MURDICA: Objection to
 5 form.
 6 THE WITNESS: As I said,
 7 there's no data on prepregnancy or
 8 post-pregnancy use of acetaminophen
 9 and the impact of autism, only on
 10 ADHD.
 11 QUESTIONS BY MR. SNIDOW:
 12 Q. All right. And then for ADHD,
 13 it sounds like you just saw the Ystrom study
 14 or Liew 2019?
 15 MR. MURDICA: Objection to
 16 form.
 17 THE WITNESS: Yeah. There's
 18 Liew 2019. There's Ystrom. There's
 19 Stergiakouli. There's Trønnes, and
 20 there's Chen. I think those are --
 21 QUESTIONS BY MR. SNIDOW:
 22 Q. But the only two that have ADHD
 23 clinical diagnosis as the endpoint are Liew
 24 2019 and --
 25 A. And Ystrom.

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1 Q. -- and Ystrom; is that right?
 2 A. Uh-huh.
 3 Q. And both of those did not find
 4 an association between prepregnancy use or
 5 post-pregnancy use and ADHD?
 6 A. Let me remind myself
 7 specifically what they found.
 8 Q. Yeah.
 9 A. Because there's also
 10 supplemental materials that need to be
 11 considered.
 12 Where am I in my report? Okay.
 13 So...
 14 Actually, I'd rather just look
 15 at the actual papers rather than try and find
 16 it in my report because I don't remember
 17 where it is.
 18 Q. Well, I actually don't want you
 19 to read the entire Ystrom and Liew paper
 20 right now.
 21 If you don't know off the top
 22 of my head, we'll do it a little bit later,
 23 okay?
 24 A. Okay.
 25 Q. All right. But am I correct,

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1 sitting here right now, you can't think of a
 2 study that showed that pre or post-pregnancy
 3 use was associated with ADHD as a clinical
 4 outcome?
 5 MR. MURDICA: Object to the
 6 form.
 7 She was looking at the study
 8 because there was something else she
 9 wanted to say about it. So if you
 10 stop her -- you can't have it both
 11 ways.
 12 THE WITNESS: Yeah. I didn't
 13 say that. I said I'd like to look at
 14 the studies to refresh my memory about
 15 the specific findings.
 16 So I'm happy to do that, but
 17 I'm not going to try and guess.
 18 QUESTIONS BY MR. SNIDOW:
 19 Q. All right. Can you go back to
 20 Bauer and Kriebel that we were just looking
 21 at before the break?
 22 A. Okay. I have it.
 23 Q. Can you turn to page 137?
 24 A. Okay.
 25 Q. It says, "There were consistent

<p style="text-align: right;">Page 342</p> <p>1 findings in the nine prospective cohort 2 studies within five cohorts suggesting 3 adverse neurodevelopmental outcomes in 4 children following APAP use in pregnancy." 5 Do you agree or disagree? 6 A. I disagree. 7 Q. Okay. Then later in the 8 paragraph it says, "The relatively modest 9 risks may be the result of residual 10 confounding, but the identification of 11 dose-response gradients, trimester effects, 12 specificity to APAP, biological plausibility, 13 as well as the findings that show 14 associations are not confounded by indication 15 for use, argue against a spurious 16 association." 17 Did I read that correctly? 18 A. You read that correctly, and 19 I'd be happy to talk about each one of those 20 and my disagreement with each one of those. 21 We've talked about already the 22 problems with the dose-response gradient 23 being based on very imperfect and flimsy 24 information. 25 The same applies for the</p>	<p style="text-align: right;">Page 344</p> <p>1 QUESTIONS BY MR. SNIDOW: 2 Q. Okay. 3 A. And I disagree. 4 Q. You disagree. 5 A. Which I said. 6 Q. With these authors here. All 7 right. 8 A. Are we done with this one? I'm 9 just trying to keep things in order. 10 Q. Yep. You can put it right 11 there. Yep. Yep. 12 (Pinto-Martin Exhibit 619 13 marked for identification.) 14 QUESTIONS BY MR. SNIDOW: 15 Q. Showing you the label for 16 valproic acid, which I will mark as 619. 17 There you go. Jim. 18 And have you read this? 19 A. I have not read the label for 20 valproic acid. I'm not an expert in 21 labeling, and it's not part of what I was 22 asked to do in my review of the epidemiologic 23 literature. So the answer is no. 24 Q. So before giving an opinion on 25 valproic acid in your report, you didn't read</p>
<p style="text-align: right;">Page 343</p> <p>1 trimester-specific effects. Although it is 2 couched as prospective in many cases, we're 3 still asking women to recall their exposure 4 for the prior, at least, trimester, if not 5 further. 6 With respect to specificity to 7 APAP, I think we talked about the lack of 8 data on ibuprofen because women are advised 9 not to take ibuprofen during pregnancy. 10 With respect to biological 11 plausibility, I have not said, but I will say 12 now, that I use biological plausibility to 13 support the evidence in epidemiologic studies 14 when I'm conducting a Bradford Hill analysis. 15 And in the absence of strong and solid 16 epidemiologic evidence, I am not willing or 17 need to consider biological plausibility. 18 Q. Okay. 19 A. And -- 20 Q. My question was just going to 21 be, do you agree or disagree? 22 MR. MURDICA: Did you finish 23 your answer? 24 THE WITNESS: I think I 25 finished.</p>	<p style="text-align: right;">Page 345</p> <p>1 the label? 2 MR. MURDICA: Objection to 3 form. 4 THE WITNESS: There would be no 5 reason for me to read the label when 6 I'm reviewing epidemiologic studies. 7 It's not what I do. 8 QUESTIONS BY MR. SNIDOW: 9 Q. Okay. 10 A. I'm not an expert in labeling. 11 Q. I just thought you might have 12 been curious. 13 MR. MURDICA: Objection to the 14 form and the commentary. 15 QUESTIONS BY MR. SNIDOW: 16 Q. Could you -- could you go to 17 page -- so this one is hard to get to because 18 the FDA did not put page numbers on here. 19 A. Of course not. 20 Q. But it's before -- if you 21 find -- flip through and find Section 8.2, 22 which is called Lactation. 23 A. 6.4. 24 MR. MURDICA: Here, if you want 25 to use this one.</p>

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1 MR. SNIDOW: Yeah, you can use
2 Jim's.
3 THE WITNESS: If I can find the
4 beginning. You did such a quick job
5 of that.
6 QUESTIONS BY MR. SNIDOW:
7 Q. And then flip just to the
8 previous page.
9 A. Okay.
10 Q. Do you see the paragraph that
11 begins "Although"?
12 A. I do.
13 Q. It says, "Although the
14 available studies have methodological
15 limitations, the weight of the evidence
16 supports a causal association between
17 valproate exposure in utero and subsequent
18 adverse effects on neurodevelopment."
19 Did I read that correctly?
20 A. That's what it says.
21 Q. Do you agree?
22 A. Again, this is a label. I have
23 absolutely no idea how a label is created. I
24 have no idea what data they are relying on
25 when they make this statement, and so I --

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1 it's not part of my review of published
2 epidemiologic literature, peer-reviewed
3 literature, so I don't -- I'm not going to
4 opine on whether I agree or disagree with
5 something that is not something I've -- I
6 typically review as part of my practice.
7 Q. Well, do you see where it says
8 "ADHD" here?
9 A. I see that it says "ADHD."
10 Q. And "Autism Spectrum
11 Disorders"?
12 A. I do.
13 Q. Do you agree -- I'm not asking
14 about the label, just do you agree with the
15 sentence, "The weight of the evidence
16 supports a causal association between
17 valproate exposure in utero and subsequent
18 adverse effects on neurodevelopment,
19 including ASD and ADHD"?
20 MR. MURDICA: Objection to
21 form.
22 THE WITNESS: Again, we've
23 talked about my opinion with respect
24 to valproic acid with respect to ASD
25 and ADHD, and that there's interesting

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1 evidence that supports the causal
2 hypothesis, but I still think there is
3 work to be done because of
4 methodologic limitations of the study.
5 And, in fact, these authors,
6 whoever they may be, acknowledged
7 those methodologic limitations right
8 at the outset of their statement.
9 QUESTIONS BY MR. SNIDOW:
10 Q. Well, the authors are the
11 makers of valproic acid, right?
12 A. I have no idea. Again, I don't
13 know how labels are created.
14 Q. You don't know that they're
15 approved by the FDA?
16 MR. MURDICA: Objection to
17 form.
18 THE WITNESS: I don't know how
19 labels are created. It's not an area
20 that I've learned anything about.
21 It's not an area I care to learn
22 anything about. It's not part of what
23 I do as an epidemiologist. It's not
24 part of my review of the
25 peer-reviewed, published literature.

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1 QUESTIONS BY MR. SNIDOW:
2 Q. Okay. I think, when we were
3 talking before, you told me you've -- you
4 weren't sure but you thought cause was most
5 likely for valproic acid.
6 Are you changing your
7 testimony?
8 MR. MURDICA: Objection to the
9 form.
10 THE WITNESS: I believe what I
11 said before, is that there is
12 interesting suggestive evidence of a
13 potential causal link and that the
14 methodologic flaws in the study, in my
15 mind, mean that we still have work to
16 do, both for -- with respect to ASD
17 and ADHD.
18 QUESTIONS BY MR. SNIDOW:
19 Q. Oh, I know there's more work to
20 do, but do you think the weight of the
21 evidence supports a causal association or
22 not?
23 MR. MURDICA: Objection to the
24 form.
25 THE WITNESS: Again, I'm --

<p style="text-align: right;">Page 350</p> <p>1 that was not part of my assignment, 2 was to -- you know, I was not asked to 3 review the evidence on valproic acid. 4 I was asked to review the evidence on 5 acetaminophen and ASD and ADHD. I'd 6 be happy to talk to you about my 7 assessment of the body of evidence 8 with respect to that.</p> <p>9 Valproic acid was in my 10 introduction to the epidemiology of 11 autism and my introduction to the 12 epidemiology of ADHD as a medication 13 that has been studied, and I think I 14 was clear on my feeling about the body 15 of evidence that I reviewed with 16 respect to that.</p> <p>17 QUESTIONS BY MR. SNIDOW: 18 Q. You don't remember telling me 19 it was most likely causal? 20 MR. MURDICA: Objection to the 21 form. 22 THE WITNESS: I remember a 23 series of questions that you asked 24 about trying to rule out confounding 25 and bias, and I don't remember</p>	<p style="text-align: right;">Page 352</p> <p>1 evidence was. Again, that was not the 2 primary focus of my review. 3 Q. You just got -- you've got two 4 sections on valproic acid in your report, 5 don't you? 6 MR. MURDICA: Objection to the 7 form. 8 THE WITNESS: I have two 9 sections. One in the background on 10 ASD, and one in the background on 11 ADHD. 12 QUESTIONS BY MR. SNIDOW: 13 Q. What's valproic acid indicated 14 for? 15 A. My understanding -- again, I am 16 not a clinical doctor, but my understanding 17 is that valproic acid is used to control 18 seizures in a woman who has seizure disorder. 19 It's used as a prophylactic, I believe, for 20 someone who has migraine headaches, and there 21 may be a couple other indications for use. 22 Interestingly, seizure 23 disorders are also implicated in autism 24 spectrum disorder. And so there may be -- 25 one of the reasons that we need to continue</p>
<p style="text-align: right;">Page 351</p> <p>1 precisely what I said, but I will 2 state again that I think that there is 3 interesting evidence and it needs 4 to -- and it's certainly stronger than 5 the evidence for acetaminophen and 6 prenatal exposure to acetaminophen and 7 ASD or ADHD because of the important 8 issue of certainty of timing and dose 9 and exposure because we have medical 10 records confirming that.</p> <p>11 And also certainty about the 12 indication for use because we have 13 medical records confirming that as 14 well.</p> <p>15 QUESTIONS BY MR. SNIDOW: 16 Q. For ADHD, the evidence 17 consisted of five small studies and a 18 meta-analysis; is that right? 19 MR. MURDICA: Objection to 20 form. 21 THE WITNESS: For valproate? 22 QUESTIONS BY MR. SNIDOW: 23 Q. Uh-huh. 24 A. I would want to go back and 25 remind myself exactly what the body of</p>	<p style="text-align: right;">Page 353</p> <p>1 to study it is that there may be a genetic 2 confounder in there that both increases the 3 risk of seizures and increases the risk of 4 autism in the offspring, and I think we need 5 to continue to look at that. 6 Q. Well, Depakote indicated for 7 acute treatment of manic or mixed episodes? 8 A. Again, I'm not an expert on 9 valproate. I don't know how it's used. You 10 read that sentence correctly. I have -- I 11 don't know. What are you asking? 12 Q. I'm asking, do you think to 13 know whether confounding by indication has 14 been controlled for you need to know what the 15 indication is? 16 A. I think that I understand the 17 primary indications for use of valproate, and 18 the studies that I've looked at looked at it 19 in relation to seizure disorder and migraine. 20 Q. Okay. But do you see here the 21 FDA is saying it's indicated for acute 22 treatment of manic or mixed episodes? 23 A. I see that that's on this 24 paper. Again, it's not something I reviewed, 25 and it's not something that the literature</p>

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1 that I reviewed discusses.
 2 So it's not relevant to my
 3 opinion because I didn't see any evidence for
 4 or against that as an indication.
 5 Q. Well, that's kind of my point,
 6 though.
 7 Don't you think that a drug
 8 that's -- that's indicated for manic episodes
 9 and bipolar disorder or psychotic features,
 10 that raises some pretty serious confounding
 11 by indications concerns, right?
 12 MR. MURDICA: Objection to
 13 form.
 14 THE WITNESS: Again, I do not
 15 have knowledge of the specific
 16 indications -- for all of the specific
 17 indications for use for valproic acid.
 18 The literature I reviewed did not
 19 address manic or mixed episodes in
 20 their analysis, so I don't -- I can't
 21 comment on it. I'm an epidemiologist.
 22 I rely -- I rely on published
 23 epidemiologic literature.
 24 QUESTIONS BY MR. SNIDOW:
 25 Q. All right. Can you look at

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1 your report, please?
 2 A. Uh-huh.
 3 Q. And can you go to page 35?
 4 A. I'm there.
 5 Q. Okay. You see "valproic acid"?
 6 A. I do.
 7 Q. Do you see that you report the
 8 indication there?
 9 A. Epilepsy, manic episodes,
 10 prophylactic -- yes.
 11 Q. So you did note that manic
 12 episodes is an indication for valproic acid,
 13 right?
 14 MR. MURDICA: Objection to the
 15 form.
 16 THE WITNESS: I -- yeah. I --
 17 I'm -- forgot that that was one of the
 18 indications, but it does say that,
 19 yes.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. Do you agree that raises grave
 22 confounding by indication concerns?
 23 MR. MURDICA: Objection to the
 24 form.
 25 THE WITNESS: I would agree

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1 that all of them do, in fact.
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. Yes.
 4 A. Epilepsy and seizure disorder,
 5 which I guess is equivalent to epilepsy, and
 6 migraine headaches, because they all have an
 7 independent association with an increased
 8 risk of autism spectrum disorder, which is
 9 precisely why I'm not willing to say, ah-ha,
 10 we found something that is definitely
 11 causally associated. I think there may be
 12 confounding that we still need to address,
 13 which is -- and I -- and I think I've said
 14 that; that there's methodologic challenges
 15 that need to be continued to -- we need to
 16 continue to study.
 17 Q. And did you say that in your
 18 report, what you just told me?
 19 MR. MURDICA: Objection to
 20 form.
 21 THE WITNESS: With respect to
 22 valproic acid?
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Yeah.
 25 Can you just take a look at

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1 that paragraph? Because you're giving me a
 2 lot of, I don't know how strong this is,
 3 confounding.
 4 Is that in your report?
 5 MR. MURDICA: Objection to the
 6 form of the question.
 7 THE WITNESS: Again, that was
 8 not the purpose of my report.
 9 The purpose of my report to --
 10 was to evaluate the epidemiologic
 11 evidence with respect to APAP exposure
 12 and ASD and ADHD. This section of my
 13 report is background information on
 14 the etiology of autism spectrum
 15 disorder. I did a similar section,
 16 background on the etiology of ADHD,
 17 and I'm reflecting on published
 18 literature that has interesting and
 19 worthy of consideration findings,
 20 valproic acid being one of them.
 21 QUESTIONS BY MR. SNIDOW:
 22 Q. Well, you say it's stronger
 23 than the association here, right? You say
 24 that in the paragraph?
 25 A. It's stronger than the

<p style="text-align: right;">Page 358</p> <p>1 association we have with APAP.</p> <p>2 Q. And do you ever, in this</p> <p>3 paragraph, mention that you have concerns</p> <p>4 about genetic confounding or confounding by</p> <p>5 indication for valproic acid?</p> <p>6 MR. MURDICA: Objection to the</p> <p>7 form.</p> <p>8 THE WITNESS: I tried to answer</p> <p>9 that question already by describing</p> <p>10 that this was not the primary focus of</p> <p>11 my report. This was background</p> <p>12 information about ASD in this case,</p> <p>13 ADHD in the other case. And the</p> <p>14 primary literature that I reviewed was</p> <p>15 the focus of my discussion of</p> <p>16 confounding by indication and</p> <p>17 confounding by genetics.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. Are you aware of any paper that</p> <p>20 was able to conclusively rule out confounding</p> <p>21 by indication for valproic acid?</p> <p>22 MR. MURDICA: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I am not aware of</p> <p>25 a paper that was able to do that.</p>	<p style="text-align: right;">Page 360</p> <p>1 Do you think that was right or</p> <p>2 wrong?</p> <p>3 A. Again, I'm not willing to</p> <p>4 comment on a label. A label is not something</p> <p>5 that I review typically. I don't know what's</p> <p>6 expected in a label. I don't know what</p> <p>7 literature they reviewed here. You're</p> <p>8 pulling out one sentence from a long</p> <p>9 document, and I'm just not willing to comment</p> <p>10 on it.</p> <p>11 It's not my area of expertise.</p> <p>12 It's not what I was asked to do in this</p> <p>13 engagement.</p> <p>14 Q. What if I put the sentence in a</p> <p>15 document that's not the label? Can you tell</p> <p>16 me if you agree or disagree with the</p> <p>17 sentence?</p> <p>18 A. Again, I think context matters,</p> <p>19 and I'm not going to give you a "yes" or "no"</p> <p>20 on something that is completely acontextual.</p> <p>21 (Pinto-Martin Exhibit 620</p> <p>22 marked for identification.)</p> <p>23 MR. SNIDOW: Okay. Can I have</p> <p>24 AA?</p> <p>25 THE WITNESS: I didn't get this</p>
<p style="text-align: right;">Page 359</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Were you able -- sorry.</p> <p>3 Can you tell me a paper that</p> <p>4 was able to conclusively rule out confounding</p> <p>5 by genetics for valproic acid?</p> <p>6 A. I cannot tell you a paper that</p> <p>7 was able to conclusively rule that out</p> <p>8 because we don't understand the total picture</p> <p>9 of genetics, and that is precisely why I'm</p> <p>10 saying we need to do additional studies.</p> <p>11 Q. Need to do additional studies</p> <p>12 before making a causal inference?</p> <p>13 A. Need to do additional studies</p> <p>14 to understand the causal pathway that exists,</p> <p>15 if it does, linking valproic acid to ASD or</p> <p>16 ADHD. We need to understand the way that</p> <p>17 the causal pathway operates.</p> <p>18 Q. Well, I know. Here's what I'm</p> <p>19 asking.</p> <p>20 Given that you couldn't rule --</p> <p>21 there's no study ruling out confounding by</p> <p>22 genetics or confounding by indication. Do</p> <p>23 you think that the makers of valproic acid</p> <p>24 were right to say, the weight of the evidence</p> <p>25 supports a causal association?</p>	<p style="text-align: right;">Page 361</p> <p>1 one marked. Does that matter? We</p> <p>2 didn't mark this one.</p> <p>3 MR. SNIDOW: I did. Someone</p> <p>4 else has got the marked one.</p> <p>5 MR. MURDICA: Oh, remember, I</p> <p>6 turned you to the right page.</p> <p>7 THE WITNESS: Oh, right.</p> <p>8 Sorry.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. All right. I'm going to show</p> <p>11 you Wiggs, which is valproic acid paper that</p> <p>12 you cite in your report. 620.</p> <p>13 Do you see this paper?</p> <p>14 A. I see this paper.</p> <p>15 Q. And is that footnote 66 in your</p> <p>16 report?</p> <p>17 A. It is, Wiggs, yes.</p> <p>18 Q. And this was published in, it</p> <p>19 looks like, 2020?</p> <p>20 A. That's correct.</p> <p>21 Q. So pretty recently?</p> <p>22 A. That's pretty recently, yes.</p> <p>23 Q. And if you go to E 233.</p> <p>24 A. Uh-huh.</p> <p>25 Q. You say, "The majority of</p>

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1 research does not adjust for many, if any,
 2 confounding factors."
 3 Correct?
 4 A. That's correct.
 5 Q. It looks like severity of
 6 maternal epilepsy. It seems like a good one
 7 to adjust for, right?
 8 MR. MURDICA: Objection to
 9 form.
 10 THE WITNESS: I think epilepsy
 11 is an important potential confounder.
 12 I think severity would be also a
 13 relevant --
 14 BY MR. SNIDOW:
 15 Q. Yeah.
 16 A. -- addition.
 17 Q. If you go to E 3238, you see
 18 where it says, "We were not able to adjust
 19 for parental diagnosis of ASD and ADHD?"
 20 A. Sorry. I just -- third, we
 21 were not able -- yes, I see that.
 22 Q. That's a pretty important thing
 23 to adjust for, right?
 24 A. I believe that parental
 25 diagnosis, which would reflect a heritability

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1 estimate, is important, yes.
 2 Q. But they didn't have it here
 3 for valproic acid, right?
 4 A. They did not, I guess.
 5 Q. And it says, "Given these
 6 disorders are heritable, this is a likely
 7 source of confounding in the present study."
 8 Right?
 9 A. That's what they say.
 10 Q. So more than just saying they
 11 weren't able to rule it out; they're saying
 12 that confounding by genetics is actually
 13 likely for valproic acid, right?
 14 A. Well, that's not -- I mean,
 15 they're not saying that. They're saying that
 16 they think that they should control for it,
 17 but they don't say likely. They don't use
 18 that term, so they think it's important.
 19 Q. Okay. Any sibling studies for
 20 valproic acid that you're aware of?
 21 A. I have not seen a sibling study
 22 on valproic acid.
 23 Can I just point out that
 24 sibling studies are actually very challenging
 25 to do? You need a very large cohort --

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1 Q. Yep.
 2 A. -- and able -- in order to be
 3 able to pull out the relevant sibling pairs,
 4 which have to be discordant for both exposure
 5 and outcome.
 6 So I don't know how common
 7 valproic acid is prescribed, but my guess is
 8 it would take an enormous cohort with a long
 9 follow-up period of multiple family members
 10 to be able to actually do a
 11 sibling-controlled analysis.
 12 Q. And why do you need such a big
 13 cohort for sibling-controlled studies?
 14 A. I just described that the
 15 relevant data for a sibling-controlled study
 16 is those individuals who are divergent on
 17 both exposure and outcome.
 18 So you can imagine how the
 19 numbers drop down once you are restricting to
 20 that. It's -- that's basically a matched
 21 analysis, and only two cells of that 2 by 2
 22 table are relevant to the question at hand.
 23 Q. And what happens when that
 24 number of discordant pairs gets too low?
 25 A. Well, I will say that in the

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1 one sibling-control study that we have for
 2 ADHD, Gustavson, the numbers went from, you
 3 know, over 100,000 women down to something
 4 like 3 -- 300-plus who were discordant on
 5 exposure. However, they were able to
 6 demonstrate an attenuation of the risk to the
 7 null.
 8 The problem we worry about with
 9 small numbers is the probability of a type 2
 10 error of missing an association, right? But
 11 if we were able to demonstrate an attenuation
 12 to the null, it wasn't a problem in that
 13 study.
 14 Q. Well, let's say that I tried to
 15 do a sibling-controlled study with five
 16 discordant pairs.
 17 Okay? Do you understand the
 18 hypothetical?
 19 A. Five discordant pairs --
 20 MR. MURDICA: Objection to the
 21 form.
 22 BY MR. SNIDOW:
 23 Q. Yeah.
 24 A. -- on outcome?
 25 Q. Yeah.

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1 A. On exposure and outcome?

2 Q. Exposure on outcome -- and

3 outcome, the relevant data.

4 A. Okay.

5 Q. Almost certainly going to get a

6 null result, right?

7 A. I have no idea. It totally

8 depends on what exposure you're talking

9 about, what outcome you're talking about.

10 Q. On five? If it's five

11 siblings, you think I'm going to get a

12 statistically significant result?

13 A. Again, I'm not going to try and

14 guess what the statistical result would be

15 based on an entirely hypothetical result. We

16 have a real result here --

17 Q. Yep.

18 A. -- with 34 discordant pairs,

19 which is at least equal to 68, probably more,

20 because there's more than one sibling in some

21 cases, and we were able to see an attenuation

22 to the null.

23 So that study had the

24 statistical power to demonstrate confounding

25 by genetics.

Page 367

1 Q. Well, you said the only concern

2 is type 2 indication, but if the study gets

3 small enough, there's going to be a type 1

4 problem, too, right?

5 A. Theoretically, I -- again, we

6 don't have data on that, and there's no point

7 in talking about it without having data on

8 that.

9 Q. But theoretically, what I said

10 is true?

11 A. I mean, we don't -- that's not

12 the situation. We have -- we have --

13 Q. We'll talk about Gustavson. I

14 just want to know, theoretically you get too

15 small of a sibling control, you're going to

16 get a type 1 error, right?

17 MR. MURDICA: Objection to

18 form.

19 THE WITNESS: I guess I would

20 ask a statistician that question.

21 I've never done a sibling-control with

22 five.

23 QUESTIONS BY MR. SNIDOW:

24 Q. Yeah.

25 A. Nor would I.

Page 368

1 Q. You wouldn't.

2 All right. For ADHD and

3 valproic acid, are you aware of any studies

4 that showed a risk ratio of more than 2.0?

5 A. Not in my recollection. Again,

6 this was not the main focus of my report, so

7 I don't have a strong recollection of a study

8 that I reviewed, but I don't remember a risk

9 ratio that high.

10 Q. Are you aware of any studies

11 for valproic acid that were able to rule out

12 confounding by indication?

13 A. I would want to look at the

14 studies that I cited to to see if any of them

15 attempted to do that. I don't recall

16 specifically.

17 Q. All right. Give me CC.

18 If you look at your report, you

19 cite one study. It's Christensen 2019.

20 A. We're talking about --

21 Q. ADHD.

22 A. -- valproic acid and ADHD now?

23 Q. Yeah.

24 A. Okay. So we're off of Wiggs?

25 Q. That's right.

Page 369

1 It's on page -- it looks like

2 73.

3 Do you see a footnote 185?

4 A. I do.

5 Q. All right. And that's

6 Christensen?

7 A. And then I cite again to Wiggs.

8 Q. Yeah.

9 You say, "Regarding valproic

10 acid exposure, a 50 percent increased risk of

11 ADHD was reported"?

12 A. Yes.

13 Q. That's a risk ratio of 1.5?

14 A. Correct.

15 Q. And then it looks like there's

16 a meta-analysis --

17 A. Uh-huh.

18 Q. -- that had a null finding?

19 A. That was -- yeah. That was a

20 meta-analysis, similar to these meta-analyses

21 in the APAP literature, that had a range

22 of neurodevelopmental outcomes, not just

23 ADHD.

24 Q. Well, it's not similar because

25 they had a null finding, right?

<p style="text-align: right;">Page 370</p> <p>1 MR. MURDICA: Objection to the</p> <p>2 form.</p> <p>3 THE WITNESS: Well, some of</p> <p>4 these studies had a null finding as</p> <p>5 well.</p> <p>6 QUESTIONS BY MR. SNIDOW:</p> <p>7 Q. You've got a meta-analysis for</p> <p>8 me that had a null finding in this</p> <p>9 literature?</p> <p>10 MR. MURDICA: Objection to the</p> <p>11 form.</p> <p>12 THE WITNESS: We've discussed</p> <p>13 some of the meta-analyses, and</p> <p>14 although they report a small</p> <p>15 statistically significant elevated</p> <p>16 risk, they are quick to point out that</p> <p>17 they -- the result could be confounded</p> <p>18 due to the heterogeneity of the</p> <p>19 outcome, due to the misclassification</p> <p>20 of exposure.</p> <p>21 So a null finding is one</p> <p>22 outcome that we need to be concerned</p> <p>23 about, but a positive finding with a</p> <p>24 qualification of the authors</p> <p>25 themselves about the reliability of</p>	<p style="text-align: right;">Page 372</p> <p>1 well. That's not true. You don't have any</p> <p>2 meta-analysis in this literature that had a</p> <p>3 null finding.</p> <p>4 MR. MURDICA: Objection to the</p> <p>5 form.</p> <p>6 THE WITNESS: I tried to answer</p> <p>7 the question by pointing out that</p> <p>8 although the meta-analyses report an</p> <p>9 elevated association, they are based</p> <p>10 on studies that are heterogenous with</p> <p>11 regard to outcome, that are based on</p> <p>12 studies with imperfect measure of</p> <p>13 exposure.</p> <p>14 So in my mind a meta-analysis</p> <p>15 is only as good as the underlying</p> <p>16 data, and as I pointed out repeatedly</p> <p>17 here, the underlying data is</p> <p>18 exceedingly weak.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Okay.</p> <p>21 A. I have to respond to one text.</p> <p>22 I apologize. It's important.</p> <p>23 (Pinto-Martin Exhibit 621</p> <p>24 marked for identification.)</p> <p>25</p>
<p style="text-align: right;">Page 371</p> <p>1 that finding is something that I take</p> <p>2 into consideration.</p> <p>3 QUESTIONS BY MR. SNIDOW:</p> <p>4 Q. I know, but you said, well,</p> <p>5 some of these meta-analyses here had a null</p> <p>6 finding as well. That's what you said,</p> <p>7 right?</p> <p>8 A. I'm talking about the --</p> <p>9 Q. Sorry. Can you focus on my</p> <p>10 question?</p> <p>11 MR. MURDICA: Whoa, whoa.</p> <p>12 MR. SNIDOW: Yeah, she's not</p> <p>13 answering this one.</p> <p>14 MR. MURDICA: You're</p> <p>15 interrupting her again.</p> <p>16 MR. SNIDOW: I know, but she's</p> <p>17 not being responsive, and you know it.</p> <p>18 THE WITNESS: I'm sorry. I'm</p> <p>19 not understanding your question.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. You said --</p> <p>22 A. I'm not trying to be</p> <p>23 nonresponsive.</p> <p>24 Q. -- well, some of the</p> <p>25 meta-analyses here had a null finding as</p>	<p style="text-align: right;">Page 373</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Okay. I'm going to show you</p> <p>3 Christensen 2013, which is 621. 2019, sorry.</p> <p>4 I said it wrong. That's the one I want.</p> <p>5 Yep.</p> <p>6 Could you turn to page 9?</p> <p>7 A. I'm sorry, I have different</p> <p>8 paging I think than you do. Limitations --</p> <p>9 MR. MURDICA: It's 9 of 13.</p> <p>10 There's a slash there. There.</p> <p>11 THE WITNESS: Oh, I see. I</p> <p>12 thought it was 913. Got it. Okay.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. Do you see limitations at the</p> <p>15 top?</p> <p>16 A. I do.</p> <p>17 Q. Do you see where it says, "Due</p> <p>18 to the observational nature of this study, we</p> <p>19 cannot rule out that the observed risk</p> <p>20 increase for ADHD is at least in part</p> <p>21 explained by the mother's health condition</p> <p>22 that triggered the prescription of valproate</p> <p>23 during pregnancy"?</p> <p>24 A. I do see that.</p> <p>25 Q. Fair to say they're describing</p>

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1 confounding by indication there?

2 A. Or perhaps comorbid conditions,

3 yes.

4 Q. Yeah. Some kind of

5 confounding?

6 A. Uh-huh.

7 Q. And they're saying they can't

8 rule that out?

9 A. That's correct.

10 Q. All right. Do you see here it

11 said for their dose data that they estimated

12 the average daily dose?

13 A. I do see that.

14 Q. And that's how they did their

15 dose-response?

16 A. And I've never quibbled with

17 the dose-response with respect to valproic

18 acid, if that's where you're going, because

19 as I've stated, they have data because it's a

20 medication that requires prescription.

21 They have data on dose and

22 timing and duration, which we do not have in

23 the acetaminophen literature.

24 Q. Oh, I actually didn't under --

25 I misunderstood your report.

Page 375

1 You think it's actually okay to

2 use average daily dose to do a dose-response

3 so long as you have really good data on

4 average daily dose?

5 MR. MURDICA: Objection to

6 form.

7 THE WITNESS: If you can

8 actually quantify dose, then I think

9 there is nothing wrong with creating a

10 measure of that actual data on dose

11 that equates with estimated average

12 daily dose.

13 To do that on the basis of

14 self-report that is retrospective, I

15 have a problem with.

16 QUESTIONS BY MR. SNIDOW:

17 Q. Okay. The conclusion here,

18 they note that "a randomized clinical trial

19 is neither feasible or ethical."

20 A. I see that, and I agree.

21 Q. And you agree?

22 A. I do.

23 Q. Yep. It says, "Replication of

24 our findings in large-scale observational

25 studies is warranted."

Page 376

1 A. And I said that right from the

2 start, that we need more data on this. We

3 need more studies. We need continued

4 examination.

5 Q. More data before what? Before

6 warning women about the risk of valproic

7 acid?

8 A. More data to understand what

9 the causal pathway is, so I wouldn't even go

10 to the next step. We need to understand the

11 causal pathway.

12 That's what epidemiology does.

13 That's why it evolves over time. That's why

14 the studies become more sophisticated.

15 As we identify confounders and

16 we're able to gather data to control for

17 those confounders, we have a more effective

18 assessment of the link between exposure and

19 outcome.

20 (Pinto-Martin Exhibit 622

21 marked for identification.)

22 QUESTIONS BY MR. SNIDOW:

23 Q. All right. I'm going to mark a

24 document as 622, which is a transcript.

25 Thank you.

Page 377

1 All right. Do you know what

2 the National Center for Toxic --

3 Toxicological Research is?

4 A. I don't. It's a national

5 center that must study toxicology, but I have

6 no knowledge of it.

7 Q. You don't even know what that

8 is?

9 A. I -- as I said, I have no

10 knowledge of it.

11 Q. All right. Do you know what a

12 science advisory board is?

13 A. I do know what a science

14 advisory board is.

15 Q. What's that?

16 A. It's a group of individuals

17 that are either volunteered or paid to serve

18 on -- as a review for a company, an

19 organization, an institute, any number of

20 those.

21 Q. If you turn the page, it's got

22 a list of attendees, and one of them is

23 division of neurotoxicology, John Talpos.

24 A. I see that.

25 Q. Do you know that guy by any

<p style="text-align: right;">Page 378</p> <p>1 chance?</p> <p>2 A. I have not ever met</p> <p>3 John Talpos.</p> <p>4 Q. If you turn to page 36.</p> <p>5 And do you see here where it</p> <p>6 says, "So there's a growing concern about the</p> <p>7 potential toxicity of in utero exposure to</p> <p>8 acetaminophen"?</p> <p>9 A. I see that.</p> <p>10 Q. And then it goes on to talk</p> <p>11 about the 2021 consensus statement.</p> <p>12 A. I see that.</p> <p>13 Q. And you know what that is, of</p> <p>14 course, the Bauer --</p> <p>15 A. I know that that's -- they --</p> <p>16 it's called a consensus statement. I have</p> <p>17 some quibble with that title, but, yes, I</p> <p>18 know what it is.</p> <p>19 Q. And then it says, "The concerns</p> <p>20 over APAP are being driven by a series of</p> <p>21 high-quality epidemiological studies."</p> <p>22 A. I see that's what these authors</p> <p>23 stated.</p> <p>24 Q. Would you agree?</p> <p>25 A. So I think that the cohort</p>	<p style="text-align: right;">Page 380</p> <p>1 They're not high quality for this purpose.</p> <p>2 Q. Okay. So you disagree with</p> <p>3 John Talpos here?</p> <p>4 A. I do.</p> <p>5 Q. Okay. Then it goes down to</p> <p>6 say -- it talks about the cumulative sample</p> <p>7 size in the study.</p> <p>8 A. Uh-huh, I see that.</p> <p>9 Q. And it says, "It's an</p> <p>10 impressive dataset highlighting this</p> <p>11 potential concern."</p> <p>12 Right?</p> <p>13 A. It says they're really very</p> <p>14 big.</p> <p>15 Q. That's what I was going to say.</p> <p>16 There's no dispute that they are monster</p> <p>17 datasets, right?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: The size of these</p> <p>21 cohort studies is substantial, partly,</p> <p>22 I might point out, because they did</p> <p>23 not have a hypothesis to start. So</p> <p>24 they were casting a wide net and they</p> <p>25 were saying, let's collect a lot of</p>
<p style="text-align: right;">Page 379</p> <p>1 studies that were designed, not for the</p> <p>2 purposes of looking at APAP exposure and</p> <p>3 neurodevelopmental outcome, were thoughtfully</p> <p>4 constructed and did a good job trying to</p> <p>5 collect data that they thought might be</p> <p>6 relevant to some potential hypothesis that</p> <p>7 they had not yet identified.</p> <p>8 So they are strong</p> <p>9 epidemiologic studies for a very general</p> <p>10 purpose. They are not strong, high-quality</p> <p>11 epidemiologic studies for the purpose of</p> <p>12 evaluating exposure to APAP during pregnancy</p> <p>13 and ASD or ADHD.</p> <p>14 Q. Do you see here he's saying the</p> <p>15 concerns over APAP?</p> <p>16 A. I see that's what they say.</p> <p>17 Q. And do you disagree?</p> <p>18 A. I disagree that these are</p> <p>19 high-quality studies with respect to the</p> <p>20 question at hand of prenatal exposure to APAP</p> <p>21 and neurodevelopmental disabilities. They</p> <p>22 were not designed for that purpose, and so</p> <p>23 they are not high-quality for that purpose.</p> <p>24 I'm not disagreeing that</p> <p>25 they're high quality for other purposes.</p>	<p style="text-align: right;">Page 381</p> <p>1 information, and we will mine that</p> <p>2 information later with specific</p> <p>3 hypotheses, which is what they're</p> <p>4 doing now.</p> <p>5 So the size of the study</p> <p>6 doesn't really matter if the data that</p> <p>7 they're trying to extract from those</p> <p>8 studies is imperfect to address the</p> <p>9 question at hand. And that's what I'm</p> <p>10 arguing.</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. But in terms of cohort size, I</p> <p>13 think the Liew cohorts are about 60,000?</p> <p>14 A. Again, I'm not disputing that</p> <p>15 they're large studies. It's -- the size of</p> <p>16 the cohort, frankly, doesn't matter if the</p> <p>17 data that they're using to derive the</p> <p>18 estimate of APAP exposure and</p> <p>19 neurodevelopmental outcome is weak or flawed.</p> <p>20 Q. All right. Let's go to page 52</p> <p>21 of this. Sorry, it's 51.</p> <p>22 Do you see where he says,</p> <p>23 "Based on what we know, it crosses the</p> <p>24 placenta and blood-brain barrier quite</p> <p>25 readily"?</p>

Page 382

1 A. I see that.

2 Q. Do you agree that APAP does

3 cross the placenta and blood-brain barrier

4 quite readily?

5 A. I've certainly read evidence to

6 that effect. So I'm not a toxicologist so

7 that's not my area of expertise, so I can't

8 really comment. I don't know what "readily"

9 means, but...

10 Q. Fair enough. You can put that

11 one aside.

12 In your report you say that the

13 association between ADHD and APAP exposure is

14 highly inconsistent, right?

15 A. That's correct.

16 Q. In fact, you say it's hard to

17 imagine any greater level of inconsistency?

18 A. I think those are my words.

19 I'd like to --

20 Q. Page 59 of your report.

21 A. Yeah, that sounds like me.

22 Q. Yeah.

23 A. Yes.

24 Q. And do you stand by that?

25 A. I do.

Page 383

1 Q. And the reason that you say

2 that -- they're inconsistent, if you turn to

3 page 101 of your report, you do a comparison

4 of some of the results in the literature.

5 Do you see that?

6 A. Yeah, this is a comparing --

7 comparing Liew 2014 and Ystrom 2017 with

8 respect to their trimester of exposure data.

9 Yeah.

10 Q. And the comparison you're doing

11 with the red and the black is you're

12 highlighting the ones that are statistically

13 significant in black and the ones that are

14 not in red?

15 A. That's correct.

16 Q. And that's why you say the

17 results are inconsistent?

18 A. It's part of the reason I say

19 the results are inconsistent.

20 Q. Yeah.

21 If you look above, it says, "A

22 comparison of the adjusted results

23 demonstrates that the results are

24 inconsistent with statistically insignificant

25 results in bold red."

Page 384

1 A. That is what I say.

2 Q. Let's look at -- you see it

3 says, "Under any two trimesters for Ystrom,"

4 there's a 1.21 and a 1.20?

5 A. 1.21 -- I see 1.2 -- oh, yes.

6 Okay. Got it.

7 Q. And you're suggesting that

8 those two results are inconsistent with one

9 another?

10 A. So when I'm evaluating

11 consistency, I'm looking at a number of

12 things. So, first of all, I'm looking at the

13 pattern across trimesters, between two

14 studies that relied on different datasets

15 and, frankly, slightly different outcomes

16 because one is looking at hyperkinetic

17 disorder and one is looking at

18 attention-deficit/hyperactivity disorder.

19 The pattern is somewhat

20 variable. The statistical significance of

21 the reported associations is somewhat

22 variable and most importantly, the data that

23 underlies those evaluations is inconsistent

24 across the two cohorts and also potentially

25 flawed.

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1 So inconsistency, in my mind,

2 encompasses an understanding of the

3 underlying data and the quality of that data.

4 It's not just about a number. In this

5 example I'm citing numbers, but my overall

6 evaluation includes all of those things.

7 Q. I get it.

8 But in this example, you're

9 citing the difference in significance between

10 those two numbers, right?

11 A. I'm citing the difference

12 across the two studies with respect to their

13 findings by trimester.

14 Q. Well, no, I'm actually

15 focused -- look at Ystrom. One study,

16 Ystrom.

17 Do you see there's a 1.21?

18 A. Which is not statistically

19 significant. I'm sorry, which is, and then

20 a -- and then a 1.20, which is not. Sorry.

21 Q. Yeah.

22 A. Yeah.

23 Q. Yeah.

24 A. That's, again, one piece of the

25 overall inconsistency. I'm talking about the

<p style="text-align: right;">Page 386</p> <p>1 pattern of associations that I see across 2 trimesters.</p> <p>3 Q. I know you're trying to say 4 that you're not saying those are inconsistent 5 now, but that's why you highlighted them in 6 red and black, right?</p> <p>7 MR. MURDICA: Objection to 8 form.</p> <p>9 THE WITNESS: So the point of 10 this illustration --</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Go ahead. I'm just looking for 13 my tabs. I'm sorry.</p> <p>14 MR. MURDICA: She can't answer 15 while you're talking to somebody else.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. Okay. Go ahead. The point of 18 the illustration?</p> <p>19 A. The point of the illustration 20 is to look at the patterns of association by 21 trimester derived from two different cohort 22 studies.</p> <p>23 That one -- the two lines that 24 you pulled out are from within a single 25 cohort, and I would argue one is significant</p>	<p style="text-align: right;">Page 388</p> <p>1 others do not." 2 Right?</p> <p>3 A. Correct.</p> <p>4 Q. And that's why here, at least, 5 you're saying that the results are 6 inconsistent?</p> <p>7 A. That's one factor that I 8 consider when I'm looking at the criterion of 9 consistency.</p> <p>10 Q. All right. Can I have the book 11 for a second?</p> <p>12 Have you seen this? Rothman?</p> <p>13 A. Rothman, yes.</p> <p>14 Q. Fair to say this is one of, if 15 not the, most authoritative texts in your 16 field?</p> <p>17 MR. MURDICA: Objection to 18 form.</p> <p>19 THE WITNESS: It's a good 20 textbook on epidemiology.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. And described as the Bible by 23 some?</p> <p>24 MR. MURDICA: Objection to 25 form.</p>
<p style="text-align: right;">Page 387</p> <p>1 and one is not, but that is not the basis for 2 my statement that the results are 3 inconsistent across the two cohorts.</p> <p>4 Q. Let's look at page 5 of your 5 report. Go back to page 5.</p> <p>6 And do you see where you say, 7 "Even ignoring issues of confounding and bias 8 that most studies fail to address, the 9 results across the studies of ASD and ADHD 10 are inconsistent"?</p> <p>11 A. I do.</p> <p>12 Q. All right. So here you're 13 ignoring issues of confounding and bias, 14 right?</p> <p>15 MR. MURDICA: Objection to 16 form.</p> <p>17 THE WITNESS: So for the 18 purpose of describing statistically 19 significant inconsistency, yes, but 20 never in overall analysis would I 21 ignore those issues.</p> <p>22 QUESTIONS BY MR. SNIDOW:</p> <p>23 Q. No, of course.</p> <p>24 And then you say, "Some report 25 statistically significant associations,</p>	<p style="text-align: right;">Page 389</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Is that right?</p> <p>3 A. I have no idea. I've never 4 heard it described as the Bible. 5 (Pinto-Martin Exhibit 623 6 marked for identification.)</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Okay. I'm going to mark 623. 9 And this is a printout of, 10 obviously, not the whole book for obvious 11 reasons, but a couple of pages I want to talk 12 about.</p> <p>13 If you could please turn to --</p> <p>14 A. Nice big paper on this one.</p> <p>15 Q. Yeah, it's a PDF printout. 16 -- page 66.</p> <p>17 A. Yes.</p> <p>18 Q. And you see here Rothman says, 19 "One mistake in evaluating consistency is so 20 common and yet wrong that it deserves special 21 mention."</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. "It is sometimes claimed that a 25 literature or a set of results is</p>

<p style="text-align: right;">Page 390</p> <p>1 inconsistent simply because some results are</p> <p>2 statistically significant and some are not."</p> <p>3 Right?</p> <p>4 A. Uh-huh.</p> <p>5 Q. It says, "This sort of</p> <p>6 evaluation is completely fallacious."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Do you agree with that?</p> <p>10 A. I think it's a bit strong, and</p> <p>11 I think that there are counterarguments to</p> <p>12 the value of using statistical significance</p> <p>13 as a way to evaluate the literature. I have</p> <p>14 a citation in my report to a recent JAMA</p> <p>15 article that describes the importance of</p> <p>16 holding to the standard when we're evaluating</p> <p>17 evidence, and I would say that in the case of</p> <p>18 imperfect data, it's even more important to</p> <p>19 consider the role of statistical</p> <p>20 significance. It will never be the only</p> <p>21 criterion by which I evaluate consistency,</p> <p>22 but I think given that we're looking at a</p> <p>23 multitude of different outcomes in this</p> <p>24 literature and different ways of assessing</p> <p>25 and combining exposure to determine dose, the</p>	<p style="text-align: right;">Page 392</p> <p>1 So, for example, the fact that</p> <p>2 one of the more robust designs to</p> <p>3 address the issue of confounding by</p> <p>4 genetics, the sibling-control design,</p> <p>5 which is one of the last studies we</p> <p>6 have published on this topic, was able</p> <p>7 to attenuate the result to the null,</p> <p>8 is very important in my consideration</p> <p>9 of the overall weight of evidence, if</p> <p>10 you will, with respect to APAP</p> <p>11 exposure and neurodevelopmental</p> <p>12 outcome.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. I promise I will talk about</p> <p>15 Gustavson with you.</p> <p>16 My question was just, in part,</p> <p>17 your analysis of consistency is doing exactly</p> <p>18 what Rothman says is completely fallacious,</p> <p>19 right?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: Again, this is a</p> <p>23 textbook. This is a teaching</p> <p>24 instrument that we use to describe to</p> <p>25 students how a -- an analysis with</p>
<p style="text-align: right;">Page 391</p> <p>1 likelihood of error is high.</p> <p>2 And so I think that completely</p> <p>3 fallacious is a strong statement. And if we</p> <p>4 were talking about a very robust and</p> <p>5 carefully measured exposure and outcome, it</p> <p>6 would be a different story.</p> <p>7 Q. And the reason you're saying</p> <p>8 you think completely fallacious is strong is</p> <p>9 because this is what you have done in your</p> <p>10 report. You've said the results are</p> <p>11 inconsistent because some are statistically</p> <p>12 significant and some are not?</p> <p>13 MR. MURDICA: Objection to the</p> <p>14 form.</p> <p>15 THE WITNESS: I made that</p> <p>16 statement, and I also made a -- I</p> <p>17 contextualize it to say that that is</p> <p>18 part of my criterion for evaluating</p> <p>19 consistency in a body of literature.</p> <p>20 I don't ever evaluate a single study</p> <p>21 in its -- on its own. That's not the</p> <p>22 way epidemiology proceeds, and so to</p> <p>23 look at the arc of evidence over time</p> <p>24 and the inconsistency of findings over</p> <p>25 time is very important.</p>	<p style="text-align: right;">Page 393</p> <p>1 integrity should proceed. And the</p> <p>2 nuance of the underlying data is</p> <p>3 completely absent here.</p> <p>4 So I would agree overall if all</p> <p>5 you're doing is looking at statistical</p> <p>6 significance out of context, then this</p> <p>7 statement is -- could be interpreted</p> <p>8 differently.</p> <p>9 I'm saying that I do not</p> <p>10 believe that the way I conducted my</p> <p>11 analysis was completely fallacious</p> <p>12 because it was contextualized in the</p> <p>13 literature itself.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Let me just ask it this way.</p> <p>16 You did this in your report?</p> <p>17 MR. MURDICA: Objection to</p> <p>18 form.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. You did that?</p> <p>21 MR. MURDICA: Asked and</p> <p>22 answered.</p> <p>23 THE WITNESS: I believe I tried</p> <p>24 to answer this. If I didn't answer</p> <p>25 it, I will try again.</p>

<p style="text-align: right;">Page 394</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Okay. Yeah, tell me.</p> <p>3 Did you do this in your report?</p> <p>4 A. Again, I'm not going to answer</p> <p>5 that question.</p> <p>6 Q. Okay.</p> <p>7 A. I'm going to describe to you</p> <p>8 what I did because you're asking me to</p> <p>9 respond to a single statement and it's taken</p> <p>10 out of context.</p> <p>11 So I don't just look at a set</p> <p>12 of results and say, I don't believe there's</p> <p>13 consistency in this body of literature</p> <p>14 because there are differences in statistical</p> <p>15 significance. I say that weighs into my</p> <p>16 consideration, the Bradford Hill</p> <p>17 consideration, of overall consistency because</p> <p>18 the underlying data is inconsistent, in and</p> <p>19 of itself, in terms of how they're measuring</p> <p>20 things and what they're measuring.</p> <p>21 And so you can't -- I can't --</p> <p>22 maybe some people can. I can't isolate</p> <p>23 myself from the reality of the data and make</p> <p>24 a statement like that. I was pointing out</p> <p>25 the data in its own context.</p>	<p style="text-align: right;">Page 396</p> <p>1 So here's the genetic</p> <p>2 confounding diagram. I want to walk through</p> <p>3 any evidence you have in support here.</p> <p>4 There's no sibling-control</p> <p>5 study for autism, is there?</p> <p>6 A. Not in this literature, there's</p> <p>7 not. There are many other sibling controls</p> <p>8 for autism, and I point them out in my</p> <p>9 literature because they're powerful ways to</p> <p>10 demonstrate and measure confounding.</p> <p>11 Q. And Leppart showed no</p> <p>12 association here?</p> <p>13 A. Leppart did not report an</p> <p>14 association for autism.</p> <p>15 Q. And your theory is that there's</p> <p>16 a gene that's associated with autism and</p> <p>17 prenatal APAP use, right?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: My theory is not</p> <p>21 that there's a gene. There is not a</p> <p>22 gene that causes autism. My theory is</p> <p>23 that there is a genetic predisposition</p> <p>24 that would increase a woman's</p> <p>25 willingness and need to use APAP</p>
<p style="text-align: right;">Page 395</p> <p>1 Q. Can you go to page 101 of your</p> <p>2 report?</p> <p>3 A. I'm there.</p> <p>4 Q. Can you find there where you</p> <p>5 told -- where you said what you just told me;</p> <p>6 that you've got to look at the underlying</p> <p>7 data when doing a consistency analysis?</p> <p>8 MR. MURDICA: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: So, again, this</p> <p>11 report --</p> <p>12 QUESTIONS BY MR. SNIDOW:</p> <p>13 Q. Just take a moment and tell me</p> <p>14 if it's there.</p> <p>15 A. I can tell you that that's not</p> <p>16 in this section of the report.</p> <p>17 Q. Okay.</p> <p>18 A. This report was a review of the</p> <p>19 literature and an attempt to apply Bradford</p> <p>20 Hill where I didn't think it was necessary.</p> <p>21 And I'm using this chart as an example of one</p> <p>22 of the flaws in the underlying data, and that</p> <p>23 is part of my evaluation of inconsistency.</p> <p>24 Q. All right. Okay. Let's go</p> <p>25 back to this chart.</p>	<p style="text-align: right;">Page 397</p> <p>1 during pregnancy.</p> <p>2 It might be that she has</p> <p>3 depression or anxiety or can't sleep,</p> <p>4 and that is tied to her genes and, in</p> <p>5 turn, that genetic profile of the</p> <p>6 woman increases the risk of her having</p> <p>7 a child on the autism spectrum.</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. That genetic profile has not</p> <p>10 been demonstrated to lead to increased use of</p> <p>11 ibuprofen; is that right?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: So we know that</p> <p>15 women who are more anxious and who</p> <p>16 have more comorbid symptoms and who</p> <p>17 have more depression use more</p> <p>18 ibuprofen during pregnancy.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Not my question.</p> <p>21 Genetics. You have not been</p> <p>22 able to show the genetics association --</p> <p>23 genetics associated with autism lead to</p> <p>24 increased use of ibuprofen; is that right?</p> <p>25 A. So we don't know what the</p>

<p style="text-align: right;">Page 398</p> <p>1 genetics are precisely that are associated 2 with autism, and so we can't test that 3 hypothesis. 4 What we can say is that because 5 we know that autism is heritable, and we know 6 that mothers are likely to have similar 7 behaviors and characteristics, that that 8 propensity to use more APAP is tied to their 9 underlying anxiety, depression, neuroticism 10 from the one study, et cetera. 11 Q. The genetics associated with 12 autism have not been demonstrated to be 13 associated with prepregnancy use of APAP; is 14 that right? 15 MR. MURDICA: Objection to the 16 form. 17 THE WITNESS: So there are some 18 negative control studies that have 19 attempted to look at prepregnancy use 20 and post-pregnancy use, but, again, 21 they are restricted to ADHD. 22 QUESTIONS BY MR. SNIDOW: 23 Q. So that's a no, right? 24 There's no study that shows 25 that the genetics associated with autism lead</p>	<p style="text-align: right;">Page 400</p> <p>1 of ADHD among offspring for prepregnancy use 2 and also for paternal use. 3 Q. Uh-huh. I know for paternal 4 use. 5 Actually, can you walk me 6 through that? You think that the paternal 7 negative control is very instructive, right? 8 A. I think it's certainly 9 important to try to use paternal use as a 10 negative control in this -- 11 Q. And you think it indicates 12 confounding by genetics, don't you? 13 A. So if the paternal use 14 prepregnancy confers an increased risk of 15 autism, it's not an intrauterine effect. It 16 means there's something else going on. 17 What that exactly is, I 18 couldn't tell you because we don't understand 19 all the genetics of autism. It could be a 20 familial factor. It could be both familial 21 and genetic, but it does point to residual 22 confounding. 23 Q. But of genetics in particular 24 is my question. Is that evidence of 25 confounding by genetics or just something</p>
<p style="text-align: right;">Page 399</p> <p>1 to prepregnancy use? 2 A. We don't have a study to 3 address that. 4 Q. And the same answer for 5 post-pregnancy use; there's no study that 6 shows the genetics associated with autism are 7 associated with post-pregnancy use? 8 A. We don't have data to support 9 that. It doesn't mean that it doesn't exist, 10 but we don't have data to support it. 11 Q. Right. 12 Well, for ADHD we do have data, 13 right? 14 A. Uh-huh. 15 Q. And so let's ask these 16 questions here. 17 Genetics associated with ADHD, 18 we have data suggesting that those are not 19 associated with prepregnancy use, right? 20 A. I think we have data on both 21 sides. We have some studies -- and I would 22 need to pull them up and look at the exact 23 citations, and some of it is in the 24 supplementary material, but I'm happy to do 25 that -- that actually shows an increased risk</p>	<p style="text-align: right;">Page 401</p> <p>1 weird's going on? 2 MR. MURDICA: Objection to 3 form. 4 THE WITNESS: Well, we don't 5 know the genetics of autism. We don't 6 know whether there is a paternal 7 contribution and a maternal 8 contribution. So we don't have the 9 data to be able to test that 10 specifically. 11 What we do have data on is to 12 show that when you do that negative 13 exposure control, the risk is there, 14 which argues for confounding 15 because -- 16 MR. MURDICA: When you -- go 17 ahead. 18 THE WITNESS: Sorry. 19 MR. MURDICA: No, I interrupted 20 you. Continue. 21 THE WITNESS: You lost me. 22 MR. SNIDOW: Jim, were you 23 going to ask me for a break? 24 MR. MURDICA: I was going to 25 say it's been an hour, when it's a</p>

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1 good point for you.

2 MR. SNIDOW: Now is good.

3 VIDEOGRAPHER: The time is

4 3:04 p.m., and we are off the record.

5 (Off the record at 3:04 p.m.)

6 VIDEOGRAPHER: The time is

7 3:18 p.m., and we're on the record.

8 QUESTIONS BY MR. SNIDOW:

9 Q. Could you turn to page -- to

10 Exhibit 623, and it's going to be the

11 page that's marked 426 maybe.

12 A. I'm sorry, what's -- so I have

13 page --

14 MR. MURDICA: I think what they

15 did is they appended a bunch of

16 different excerpts together.

17 THE WITNESS: Oh, so it's way

18 farther along? Got it. So I'm sorry,

19 what number?

20 QUESTIONS BY MR. SNIDOW:

21 Q. 426.

22 A. Got it.

23 Q. And Jim is exactly right.

24 A. All right.

25 Q. Do you see where it says --

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1 MR. MURDICA: Can you read that

2 back?

3 QUESTIONS BY MR. SNIDOW:

4 Q. Do you see where it says

5 sibling-controls?

6 A. I do.

7 Q. It says, "Matching study

8 subjects with siblings may be used in both

9 cohort and case-control studies to control

10 for shared genetic and environmental

11 factors"?

12 A. I see that.

13 Q. And do you agree that it --

14 sibling controls do control both for genetic

15 factors and for shared environmental factors?

16 A. So, yes. And I think the

17 emphasis on shared environmental factors is

18 important because it's critical that those

19 environmental factors don't change from

20 pregnancy to pregnancy, and there's times

21 when they do.

22 Q. Yep.

23 If a sibling-controlled study

24 did show statistically significant results,

25 do you agree that would be compelling

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1 evidence that confounding by genetics is not

2 the explanation?

3 MR. MURDICA: Objection to

4 form.

5 THE WITNESS: If a

6 sibling-control showed an effect, so

7 even though it was not an intrauterine

8 effect, you still saw effect -- an

9 effect, that would point to genetics

10 as a confounder.

11 QUESTIONS BY MR. SNIDOW:

12 Q. No, no, no.

13 A. I'm sorry, I didn't understand

14 your --

15 Q. Yeah, that's okay.

16 A. -- hypothetical.

17 Q. All right. Here's the mom,

18 right? She's got whatever genetics she has,

19 right?

20 A. Okay.

21 Q. And then she's got two kids?

22 A. Right.

23 Q. And they can be boys, they can

24 be girls, in the sibling studies. It doesn't

25 matter, but she's got two kids. And one is

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1 exposed, and the other is not exposed.

2 This is how you do a

3 sibling-control trial, right?

4 A. This is correct, right.

5 Q. And my question is, if the

6 exposed child has an increased risk of the

7 disease --

8 A. Uh-huh.

9 Q. -- that is compelling evidence

10 that the mom's genetics is not confounding

11 the association?

12 MR. MURDICA: Objection to

13 form.

14 THE WITNESS: So the exposed

15 child has an increased risk, and the

16 unexposed child does not.

17 QUESTIONS BY MR. SNIDOW:

18 Q. Okay.

19 A. So that's your discordant pair

20 right there.

21 Q. Yep.

22 A. So they're discordant on

23 outcome, and they're discordant on exposure.

24 Q. Right.

25 A. And I would say that is

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1 evidence that genetics does not entirely
 2 explain the association, and that -- and yet,
 3 as we know, genetics is not everything.
 4 It's, you know -- heritability is not one.
 5 And so it then has us look at
 6 what factors might explain the association.
 7 Q. All I'm asking is, this would
 8 be strong evidence against genetic
 9 confounding?
 10 MR. MURDICA: Objection to
 11 form.
 12 THE WITNESS: Strong? I mean,
 13 I think it depends on the study, but
 14 it's evidence against genetic
 15 confounding, I'll give you that.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. Thank you.
 18 In your report you cite
 19 von Ehrenstein as an example of a
 20 sibling-controlled study that I think you
 21 thought was done pretty well. It's on
 22 smoking.
 23 MR. MURDICA: Objection to
 24 form.
 25 THE WITNESS: Correct.

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1 (Pinto-Martin Exhibit 624
 2 marked for identification.)
 3 QUESTIONS BY MR. SNIDOW:
 4 Q. And I'm going to show it to
 5 you. I'm going to mark this as 624, and it's
 6 tab R in case anyone cares. There you go.
 7 All right. And this is
 8 von Ehrenstein, and they used a
 9 sibling-controlled study as a risk factor?
 10 A. Uh-huh.
 11 Q. And what they did was they
 12 found that heavy prenatal smoking was related
 13 to an odds ratio of, it looks like, 1.55 for
 14 autism?
 15 A. Uh-huh.
 16 Q. And that's their main analysis,
 17 right?
 18 A. Again, I would want to look
 19 through and see, but that sounds right.
 20 That's usually what you quote in your
 21 abstracts, yeah.
 22 Q. And that's going to be
 23 analogous when we look at it to the main
 24 Gustavson analysis?
 25 A. Uh-huh.

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1 Q. Yeah.
 2 Then it says, "In the sibling
 3 comparison, the odds ratio for heavy smoking
 4 was similarly elevated, but the confidence
 5 interval was wide"?
 6 A. Uh-huh.
 7 Q. And do you interpret that to
 8 mean was not statistically significant?
 9 A. I don't know.
 10 Q. We can look. Look at 733.
 11 Do you see that there where
 12 they report the sibling controls?
 13 A. I'm just studying it. Yep.
 14 Q. Yeah.
 15 And my question, so you know,
 16 is going to be no results across the board?
 17 A. First -- within the sibling --
 18 I'm sorry, I'm not understanding your
 19 question. Within the sibling cohort, there's
 20 no results across the board is what your
 21 statement is?
 22 Q. Null results?
 23 A. Oh, null results across the
 24 board.
 25 Okay. I would say -- let's

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1 see. Null results throughout.
 2 Q. All right. If you turn to
 3 page 731, the authors of this study say,
 4 "While the sibling comparison should adjust
 5 for shared familial factors by design, the
 6 approach has several limitations."
 7 Do you agree with that?
 8 MR. MURDICA: Object to the
 9 form.
 10 THE WITNESS: I think there
 11 are -- again, this is a general
 12 statement, but I think there are
 13 problems with sibling controls. It's
 14 not a perfect measure of genetics.
 15 It's probably as good as it
 16 gets, but, again, because we don't
 17 know all of the risk factors for
 18 something like autism spectrum
 19 disorders or ADHD, it's hard to know
 20 whether we are full -- fully
 21 controlling for everything.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. It says that they're prone to
 24 exposure misclassification?
 25 A. Again, I'd want to understand

<p style="text-align: right;">Page 410</p> <p>1 why they're saying that, but that is a</p> <p>2 possibility in sibling controls.</p> <p>3 Q. And exposure misclassifications</p> <p>4 when they're nondifferential bias results</p> <p>5 toward the null, right?</p> <p>6 A. So in --</p> <p>7 Q. That's just textbook, right?</p> <p>8 A. In general, exposure</p> <p>9 misclassification, when it's not</p> <p>10 differential, reduces the measure of</p> <p>11 association.</p> <p>12 Q. And that can lead to false</p> <p>13 negatives?</p> <p>14 A. It can, and -- but I think it's</p> <p>15 important to understand the evidence that is</p> <p>16 behind that. Again, as I always say, it's</p> <p>17 not -- you can't -- that's a textbook</p> <p>18 definition, right? And then the context of</p> <p>19 the study and the measurement of exposure</p> <p>20 matters.</p> <p>21 Q. Then it says,</p> <p>22 "Sibling-controlled studies usually have less</p> <p>23 power and generalizability."</p> <p>24 Right?</p> <p>25 A. Well, the less power is a</p>	<p style="text-align: right;">Page 412</p> <p>1 we're comparing the full cohort with the</p> <p>2 sibling discordant group and seeing if</p> <p>3 there's a difference.</p> <p>4 And they're saying they're</p> <p>5 generally consistent with the full cohort,</p> <p>6 but where they're not, we're showing an</p> <p>7 intrauterine effect, and we're implicating</p> <p>8 genetics.</p> <p>9 We have already talked about</p> <p>10 the limited sample size available to us, and</p> <p>11 of course the smaller the sample size, the</p> <p>12 less imprecise the estimates.</p> <p>13 But, again, I will point out</p> <p>14 that even with a relatively limited sample</p> <p>15 size, Gustavson was able to demonstrate</p> <p>16 genetic confounding and to attenuate the</p> <p>17 association to the null.</p> <p>18 Q. Okay. We'll get there.</p> <p>19 You actually -- just you</p> <p>20 said -- you said of course the smaller the</p> <p>21 sample size, the less imprecise the</p> <p>22 estimates? I think you meant --</p> <p>23 A. I'm sorry, I misspoke.</p> <p>24 Q. Do you mind just saying it for</p> <p>25 me?</p>
<p style="text-align: right;">Page 411</p> <p>1 function of what we talked about before,</p> <p>2 right? You are reducing down to siblings who</p> <p>3 are discordant on exposure and outcome. So</p> <p>4 that is going to reduce the study power by</p> <p>5 virtue of the sample size.</p> <p>6 And less generalizability, I'd</p> <p>7 want to think about that. I'm sure exactly</p> <p>8 why they're saying that.</p> <p>9 Q. Yeah, don't worry about that</p> <p>10 one. I just want to know about the power.</p> <p>11 Sibling-controlled studies</p> <p>12 usually have less power, right?</p> <p>13 A. Sibling-control studies usually</p> <p>14 have less power. I think that's --</p> <p>15 Q. 732 on Ehren -- von Ehrenstein,</p> <p>16 at the top right -- top of the right-hand</p> <p>17 column, it says, "The sibling-comparison</p> <p>18 design are usually consistent with the</p> <p>19 findings from the full cohort. The small</p> <p>20 number of discordant siblings resulted in</p> <p>21 imprecise estimations, thus limiting our</p> <p>22 abilities to evaluate family-based</p> <p>23 confounding."</p> <p>24 Right?</p> <p>25 A. So what they're saying there is</p>	<p style="text-align: right;">Page 413</p> <p>1 A. So the smaller the sample size,</p> <p>2 the more likely we have imprecision in the</p> <p>3 estimate of the measure of association.</p> <p>4 Q. And that can lead to false</p> <p>5 negatives?</p> <p>6 MR. MURDICA: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: It can lead to</p> <p>9 false negatives. It doesn't always</p> <p>10 lead to false negatives, right? And I</p> <p>11 think where we have a finding, we are</p> <p>12 showing that even a small sample can</p> <p>13 demonstrate a significant impact.</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Let's turn to 735. The</p> <p>16 von Ehrenstein authors say, "Sibling design</p> <p>17 has less statistical power and requires a</p> <p>18 relatively large number of discordant pairs."</p> <p>19 A. I think I just said that.</p> <p>20 Q. Yeah, I agree.</p> <p>21 Then it says, "Thus sample size</p> <p>22 limitations did not allow us to assess the</p> <p>23 role of familial confounding as intended."</p> <p>24 Right?</p> <p>25 A. Uh-huh.</p>

<p style="text-align: right;">Page 414</p> <p>1 Q. So what they're saying there is</p> <p>2 even though they got null results for the</p> <p>3 sibling-controlled studies, they're not sure</p> <p>4 whether that indicates genetic confounding or</p> <p>5 not, right?</p> <p>6 A. So, again, that's a type 2</p> <p>7 error, right? They're saying we don't have</p> <p>8 the power to really rule in or rule out, and</p> <p>9 that is different from saying we found an</p> <p>10 association that attenuated the full cohort.</p> <p>11 Q. I don't know. Look at the</p> <p>12 table again. Look at Table 1.</p> <p>13 A. I saw Table 1, but what --</p> <p>14 Q. All right. So they got no</p> <p>15 results?</p> <p>16 A. Right. But what they're</p> <p>17 saying -- read their sentence again.</p> <p>18 Q. Uh-huh.</p> <p>19 A. "The sibling design has less</p> <p>20 statistical power, requires a relatively</p> <p>21 large number of discordant pairs."</p> <p>22 So they're saying we got a null</p> <p>23 result, but we're not sure that that wouldn't</p> <p>24 be different in if -- were we to have a large</p> <p>25 sample size.</p>	<p style="text-align: right;">Page 416</p> <p>1 they worth the effort?"</p> <p>2 Right?</p> <p>3 A. I have seen this.</p> <p>4 Q. And you cite this in your</p> <p>5 paper?</p> <p>6 A. I did.</p> <p>7 Q. And if you turn to page 740,</p> <p>8 they start talking about von Ehrenstein.</p> <p>9 A. Uh-huh.</p> <p>10 Q. And they say, "If, on the other</p> <p>11 hand, an association remains, we have not</p> <p>12 shown that it's causal, but we have known</p> <p>13 that it is not entirely explained by</p> <p>14 confounding shared by the siblings."</p> <p>15 I assume you fully agree?</p> <p>16 A. Yes.</p> <p>17 Q. It says, "It is thus imperative</p> <p>18 that we have sufficient power to demonstrate</p> <p>19 such a null finding."</p> <p>20 A. Uh-huh.</p> <p>21 Q. All right. They say that was</p> <p>22 the weakness in von Ehrenstein, right?</p> <p>23 They say, "Only 58 of those</p> <p>24 were exposed to prenatal smoking, and many of</p> <p>25 them were likely from uninformative pairs."</p>
<p style="text-align: right;">Page 415</p> <p>1 Right.</p> <p>2 Q. Right. Yep.</p> <p>3 And the sample size in</p> <p>4 von Ehrenstein, the number of discordant</p> <p>5 pairs was -- and you're going to have to help</p> <p>6 me here. It looks like discordant on --</p> <p>7 A. Yeah, this is hard to do.</p> <p>8 Q. Yeah. But I think discordant</p> <p>9 on both is 64.</p> <p>10 A. I can spend some time, but I</p> <p>11 think so. Smoking during pregnancy.</p> <p>12 Yeah, the maximum is 64. Yeah.</p> <p>13 (Pinto-Martin Exhibit 625</p> <p>14 marked for identification.)</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. That's what I thought, too.</p> <p>17 Okay.</p> <p>18 Then let's look at Frisell,</p> <p>19 which I think you cite as well, and I think</p> <p>20 you recently added it to your reliance list.</p> <p>21 I'm going to mark as 625. There you go.</p> <p>22 You've seen this one before?</p> <p>23 A. Uh-huh.</p> <p>24 Q. And the title is "Invited</p> <p>25 commentary: Sibling-comparison designs, are</p>	<p style="text-align: right;">Page 417</p> <p>1 Correct?</p> <p>2 MR. MURDICA: Object to the</p> <p>3 form.</p> <p>4 THE WITNESS: So it's 58 who</p> <p>5 are discordant on exposure, so I think</p> <p>6 that our 64 guesstimate is incorrect.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Yeah, I didn't get that either.</p> <p>9 But it's -- I didn't understand it.</p> <p>10 A. It's less. It's --</p> <p>11 Q. But they're saying it's 58,</p> <p>12 which is less.</p> <p>13 A. 58 is dis -- discordant on</p> <p>14 exposure. Then you also have to say how many</p> <p>15 were discordant on outcome.</p> <p>16 Q. Yeah.</p> <p>17 A. So it's going to be much</p> <p>18 smaller, so it's -- you know, I don't know</p> <p>19 what it would be. Anyway, it's small.</p> <p>20 Q. Yeah.</p> <p>21 It says, "The results and broad</p> <p>22 confidence limits were consistent with both</p> <p>23 increased and decreased association compared</p> <p>24 with the full cohort."</p> <p>25 Right?</p>

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1 A. That's a hard sentence to
 2 understand, but that is what it says. In
 3 other words, they couldn't -- they couldn't
 4 rule out or rule in, yeah.
 5 Q. All right. So they're saying
 6 based on the sample --
 7 A. No association was possible,
 8 yeah.
 9 Q. Based on the sample size in von
 10 Ehrenstein, they weren't able to say whether
 11 there was an actual increased or decreased
 12 association in the sibling-control part of
 13 the study.
 14 A. Right.
 15 Q. Is that right?
 16 A. That's what they said, correct.
 17 Q. Then it says, "Concluding
 18 remarks, sibling comparisons do indeed add
 19 unique value but only when the power is
 20 moderate to high."
 21 A. Right.
 22 Can we look at what they also
 23 say, which is, "Could we have foreseen this
 24 lack of power"? And they say, you know, "For
 25 binary exposure and outcome, it will be

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1 decided by the number of doubly discordant
 2 pairs," which is what we just talked about.
 3 "This, in turn, depends on the prevalence of
 4 exposure and outcome."
 5 So they, too, are stating what
 6 I've been stating over and over again; that
 7 just relying on a statistical assessment of
 8 the ability to prove or disprove the null
 9 hypothesis is an imperfect way to do it, and
 10 you have to consider what you're measuring,
 11 how reliable that measure is, how prevalent
 12 that exposure is, et cetera.
 13 Q. Okay. My question, though, do
 14 you see where they say "only when the power
 15 is moderate to high"?
 16 A. I see that.
 17 Q. And that's true; you need
 18 moderate to high power for sibling
 19 comparisons to have value?
 20 A. And, again, you can't know that
 21 in advance, and it depends, as they just
 22 said, on the prevalence of the exposure. So
 23 that's one of the reasons they're so
 24 challenging, because you can't do a power
 25 analysis in advance, really.

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1 Q. Okay. Let's look at -- all
 2 right. Do you see the diagram?
 3 A. Mom --
 4 Q. Yeah.
 5 A. -- discordant on exposure --
 6 Q. Yeah.
 7 A. -- and one child has autism, I
 8 think we're talking about here.
 9 Is that right?
 10 Q. Yeah.
 11 A. Or ADHD?
 12 Q. Yeah.
 13 Brandlistuen found this for
 14 communication scores, externalizing behavior,
 15 internalizing behavior and higher activity
 16 levels, right?
 17 A. Among the sibling control,
 18 Brandlistuen was able to show that the
 19 significant elevated effect remained. So
 20 arguing against an intrauterine effect.
 21 However, I will point out that
 22 the screening tools that they used are not
 23 directly relevant to a diagnosis of ASD or
 24 ADHD, and they themselves in the paper call
 25 for a more refined analysis that's based on

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1 diagnostic outcome.
 2 Q. And sorry, I think you misspoke
 3 again.
 4 You said that argues against
 5 intrauterine effect. Did you mean argues
 6 against genetic confounding?
 7 A. I'm sorry, yes.
 8 Q. Is that right?
 9 Just say it again. They found
 10 a result that argued against a genetic
 11 confounding?
 12 A. They found a consistent effect
 13 among exposed and unexposed, which argues
 14 against the genetic effect.
 15 Q. Thank you.
 16 And --
 17 A. However --
 18 Q. Yeah, I get that it's not a --
 19 it doesn't -- your point is it doesn't use
 20 ASD and ADHD clinical diagnoses of outcomes,
 21 right?
 22 A. Right. These are -- these are
 23 screening outcomes that are not directly
 24 relevant to a diagnosis. And as I stated
 25 before, when we use a screening tool, it's to

<p style="text-align: right;">Page 422</p> <p>1 identify children in this case who might be 2 at risk for a diagnosis. And so we set a 3 very high sensitivity in order to get anyone 4 who might be at risk, and we then subject 5 them to further evaluation to determine the 6 specific diagnosis. 7 I think it's really important 8 to understand that in this literature. 9 Q. Okay. So this -- what I've 10 drawn here, this is what Brandlistuen found? 11 A. Yeah. I'd like to pull it up 12 and look specifically at the betas that they 13 described, if we want to get into 14 Brandlistuen, because the clinical 15 significance of those findings is very 16 questionable in my mind. 17 Q. That's all right. 18 A. You don't want to look at it? 19 Q. Not right now. I might later. 20 MR. SNIDOW: Actually, we'll 21 you pull it out? Actually, can I see 22 Brandlistuen? I'm not sure if we 23 marked this one. You might be on a 24 wild goose chase. 25 (Pinto-Martin Exhibit 626</p>	<p style="text-align: right;">Page 424</p> <p>1 doubles the risk of language problems in 2 3-year-old children." 3 Did I read that correctly? 4 A. You read that correctly. That 5 does not speak to the clinical significance 6 of those findings with respect to a 7 diagnostic outcome of ASD or ADHD. 8 Q. Well, then it does a comparison 9 with smoking. It says, "For comparison, the 10 effect of a well-established association 11 between prenatal smoking and externalizing 12 behavior problems has been reported to be as 13 small as .07 in a recent study using sibling 14 design." 15 Right? 16 A. Again, it does not speak to the 17 clinical significance of this finding with 18 respect to a diagnostic outcome, which is 19 what I was evaluating in this literature. 20 Q. Again, what it's saying -- 21 A. We see it in smoking, we see it 22 in this, but it doesn't speak to the clinical 23 significance, what is the construct validity 24 of a communication problem with respect to 25 ADHD or an externalizing behavior problem.</p>
<p style="text-align: right;">Page 423</p> <p>1 marked for identification.) 2 QUESTIONS BY MR. SNIDOW: 3 Q. All right. I'm going to mark 4 it as 626. If we end up with two 5 Brandlistuens, it's not the end of the world. 6 All right. This is what we 7 were just talking about? 8 MR. MURDICA: Objection to 9 form. 10 THE WITNESS: This is the 11 Brandlistuen study. 12 QUESTIONS BY MR. SNIDOW: 13 Q. Turn to page 1711. 14 Do you see where it says, "A 15 major strength in the study was the large 16 sample size, enabling sibling-control 17 design"? 18 A. I do see that. 19 Q. And if you look over here, 20 since you wanted to talk about clinical 21 terms, it says, "In clinical terms, these 22 results suggest that exposure to paracetamol 23 for more than 28 days during fetal life 24 increases the risk of adverse psychomotor and 25 behavioral outcomes by almost 70 percent and</p>	<p style="text-align: right;">Page 425</p> <p>1 Again, I would like to look at 2 the size of those effects with respect to a 3 diagnosis. We don't know. 4 Q. All right. While we're here, 5 under the Discussion section on 1710, you see 6 it says, "We found no association between 7 ibuprofen on the same neurodevelopmental 8 outcomes"? 9 A. I did -- I do see that. 10 Q. It says, "Which suggests a 11 specific effect of paracetamol less likely to 12 be confounded by indication"? 13 A. I do see that. Again, my 14 earlier point about the paucity of ibuprofen 15 consumption by pregnant women, because 16 they're told not to take it, I think renders 17 the comparison less than informative. And 18 they had a yes/no measure of that exposure. 19 It's just not compelling evidence in my mind. 20 Q. Brandlistuen had almost a 21 thousand discordant pairs? If you look at 22 1704. 23 A. So they had 700 -- no, they 24 had -- sorry, 805 who were discordant on 25 exposure 1 to 27 days, and they had 134 who</p>

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1 were discordant on greater than and equal to
 2 28 days, which is what we're talking about.
 3 But that does not address
 4 the -- the discordant on -- discordance on
 5 outcome, which, as we've said, are the only
 6 relevant pairs when you do the analysis. It
 7 doesn't tell us here how many were discordant
 8 on outcome, and it's because it's a
 9 regression analysis. It's not as easy to
 10 figure it out as when it's a matched, you
 11 know, sort of 2-by-2 table where you can look
 12 at the cells that actually contribute.
 13 So --
 14 Q. Based on this, can you say
 15 whether this was a large enough
 16 sibling-control study to give accurate
 17 results?
 18 A. I can't, because I don't know
 19 the number of sibling discordant on these
 20 outcomes that they reported, and I couldn't
 21 find it anywhere in the paper.
 22 Furthermore, as I've said
 23 repeatedly, the outcome is not relevant to my
 24 opinion about whether prenatal APAP is
 25 associated with ASD or ADHD.

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1 And so I think -- you know, I
 2 can't -- I can't make a judgment.
 3 I will say one more thing that
 4 they also mention in their discussion of the
 5 results, which is that the MoBa cohort had a
 6 very high loss to follow-up. So the
 7 participant -- the participation rate was
 8 only about 40 percent, and what we know about
 9 participation in longitudinal cohort studies
 10 is that women with higher levels of anxiety
 11 are more likely to be retained in
 12 longitudinal studies, and we have a lot of
 13 good data supporting that.
 14 Why? Because they're anxious,
 15 and they want to see what's happening with
 16 their child, and they want to bring their
 17 child back in for a checkup.
 18 And so we have, at the end of
 19 the day, a highly selected population that
 20 have completed this series of long-term
 21 evaluations over time. Again, I think that's
 22 relevant to interpretation of the data.
 23 Q. All right. Could you turn to
 24 page 7 of your report?
 25 A. Hold on.

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1 7. Okay.
 2 Q. Do you see in your report the
 3 sample size for Brandlistuen?
 4 A. On page 7?
 5 Q. Yep. I think so.
 6 A. I'm not seeing it.
 7 Q. No?
 8 A. Here I'm talking about
 9 ecological studies on page 7. I start to
 10 talk about retrospective --
 11 Q. Oh, sorry. You know what it
 12 is? It's page 7 of your appendix.
 13 A. Okay. The appendix discussion?
 14 Okay.
 15 Okay. So I have them -- so
 16 it's the first page of my appendix. Is that
 17 what we're looking at?
 18 Q. Well, it's page 7 of your --
 19 A. Well, it's page 27 in mine, so
 20 the numbering is different. Are you looking
 21 at the chart, or are you looking at the
 22 actual narrative?
 23 Q. It says, "Appendices to Expert
 24 Report of Jennifer Pinto-Martin," and it
 25 should be page 7. It's a chart.

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1 A. Okay. So it's a chart. I'm
 2 sorry. I have both. I have a chart and a
 3 narrative.
 4 Page 7, I'm there.
 5 Q. All right. Do you see
 6 Brandlistuen?
 7 A. I do.
 8 Q. You report the sample size as
 9 the discordant pairs, right?
 10 A. So that's what they reported,
 11 so that was all I was able to pull out of
 12 their paper --
 13 Q. I'm not criticizing that.
 14 A. -- that's 800-and-something
 15 discordant pairs.
 16 Q. If you go to page 74 of your
 17 report.
 18 A. Yep.
 19 Q. You talk about Gustavson?
 20 A. Gustavson 2021, yes.
 21 Q. You report the population is
 22 21,448?
 23 A. Correct.
 24 Q. You report the sibling-control
 25 result and the results?

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1 A. Uh-huh.

2 Q. But you never report the

3 discordant pair numbers in your table here?

4 A. Not in the table, but in my

5 overview of Gustavson in the narrative, I do.

6 Q. But you don't think you

7 should -- I mean, I read this, and I said,

8 wow, Gustavson had 21,000 people in the

9 sibling control.

10 That's not accurate, right?

11 A. No, that's not accurate.

12 Q. Okay. Do you report any

13 limitations for the Gustavson paper?

14 A. Well, certainly, because the

15 Gustavson paper is based on the MoBa cohort,

16 and that's not -- you know, as I said from

17 the very beginning, that study was not

18 designed to assess the relationship between

19 APAP and neurodevelopmental outcome.

20 Q. Let's look at page 76 of your

21 report.

22 MR. MURDICA: You interrupted

23 her again.

24 MR. SNIDOW: I didn't mean to.

25 I thought she was done.

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1 QUESTIONS BY MR. SNIDOW:

2 Q. All right. Can you go to 76 of

3 your report?

4 A. I see, yeah.

5 Q. This is Gustavson?

6 A. Uh-huh.

7 Q. And where -- you just told me

8 you reported the number of discordant pairs?

9 MR. MURDICA: Is that a

10 question?

11 QUESTIONS BY MR. SNIDOW:

12 Q. Uh-huh.

13 Didn't you just tell me that

14 your reported --

15 A. I did, and I thought I had

16 reported it in my narrative. I do not see

17 it, but I could cite it to you.

18 Q. That's a pretty important

19 omission, right? Because that's the sample

20 size that determines the power of that

21 analysis, right?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: That is the

25 sample size that determines the power

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1 of that analysis. And as I've stated

2 repeatedly, although there were only

3 34 discordant on both, the sibling

4 then doubles that to 68, and at least

5 68 because there were additional

6 siblings included in the analysis, and

7 they found an attenuation of risk.

8 So when you find that a

9 confounding estimate reduces the

10 association to the null, the study

11 power is not what you're worried about

12 anymore. You've shown the

13 association, and that's what we're

14 after.

15 QUESTIONS BY MR. SNIDOW:

16 Q. Yeah.

17 But my question is this. For

18 Brandlistuen, you noted the number of

19 discordant pairs, right? Because that's what

20 determines the power of the study, right?

21 Is that true?

22 A. I am surprised that I don't

23 have the number for Gustavson in here because

24 I truly thought I did. So if it was omitted,

25 it was omitted in error. It was not an

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1 intentional omission.

2 Q. Okay. Well, do you report any

3 limitations for Gustavson?

4 A. Again, when I describe the

5 cohort in general, I do admit that the --

6 because the cohorts were not designed to

7 measure this association, the possibility of

8 recall bias with respect to exposure is

9 always there.

10 Q. No, but there -- they're on

11 that page. When you're describing Gustavson,

12 do you ever say limitations of this study

13 include, blah-blah-blah-blah-blah, like you

14 do for everything else?

15 MR. MURDICA: Objection to

16 form.

17 THE WITNESS: So Gustavson is

18 the pinnacle of a series of studies

19 that were done on the MoBa cohort, and

20 when you understand how epidemiology

21 involved -- evolved, you understand

22 that, you know, irrespective of the

23 methodologic challenges, investigators

24 are trying to do a better and better

25 job to demonstrate an association, and

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1 that's what's going on here.

2 QUESTIONS BY MR. SNIDOW:

3 Q. My question was, do you ever

4 describe any limitations of the Gustavson

5 study?

6 MR. MURDICA: Objection to

7 form.

8 QUESTIONS BY MR. SNIDOW:

9 Q. Here, on page -- on page 76?

10 A. On page 76, I do not see any

11 direct critique of the Gustavson paper.

12 Q. Do you agree that for many of

13 the other studies, you provided extensive

14 critiques of the studies?

15 MR. MURDICA: Objection to

16 form.

17 THE WITNESS: So, again, I do

18 agree with that, but can I just point

19 out that because I describe many other

20 studies from the MoBa cohort, I am

21 stating the --

22 QUESTIONS BY MR. SNIDOW:

23 Q. And, ma'am, I'm not trying to

24 be disrespectful. I just am trying to get an

25 exhibit number.

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1 MR. MURDICA: Let the record

2 reflect that Dr. Pinto-Martin is doing

3 her best to answer the question and

4 you're not paying attention, and

5 you're having conversations and it's

6 making it -- it's making it hard for

7 me to defend it, it's making her --

8 hard for her to testify, and she just

9 expressed that.

10 QUESTIONS BY MR. SNIDOW:

11 Q. Okay. I apologize. That

12 wasn't my intention.

13 Could you look at --

14 A. Could I finish what I was

15 saying?

16 Q. Well, sure. I didn't stop you.

17 A. What I do when I review a body

18 of literature is discuss the study design for

19 the cohort from which the data is derived,

20 and I do that in many places in this report.

21 It does not happen to appear on my discussion

22 of Gustavson, which, as I said, is the latest

23 study from a whole series that emerged from

24 the MoBa cohort.

25 Q. Gustavson adds sibling controls

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1 to that body of literature, right?

2 A. It does.

3 Q. You don't report any

4 limitations resulting from sibling-controlled

5 analysis, right?

6 MR. MURDICA: Object to form.

7 QUESTIONS BY MR. SNIDOW:

8 Q. Any?

9 MR. MURDICA: Objection to the

10 form.

11 THE WITNESS: To Gustavson

12 sibling control?

13 QUESTIONS BY MR. SNIDOW:

14 Q. Correct.

15 A. I -- in this -- in this section

16 right here, I do not critique Gustavson. I

17 think it's a very important study. I

18 obviously rely on it heavily because, as I

19 pointed out repeatedly, the way epidemiology

20 evolves is over time, with increased

21 attention to detail and to addressing

22 confounding. And only because the MoBa

23 cohort continued to recruit siblings and had

24 data on outcome was Gustavson able --

25 Gustavson and his coauthors, who prior had

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1 reported had an increased risk, were able to

2 show that it was confounded by genetics

3 because the cohort evolved and they had data

4 on siblings.

5 Q. Can you look at Exhibit 605 for

6 me?

7 A. 605 is what?

8 Q. It's the reference manual.

9 A. Okay. Hold on. Okay.

10 Q. Do you see where it says,

11 "What's the power of the test?"

12 A. I'm sorry, what page are we

13 looking at?

14 Q. 253.

15 A. Will you give me a page?

16 Q. Yes, that would have been a

17 good -- that would've been a good thing to

18 tell you. I agree.

19 A. 253. "What is the power of the

20 test?"

21 Q. It says, "When a p-value is

22 high, the findings are not significant, and

23 the null hypothesis is not rejected."

24 True?

25 A. That's what it says.

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1 Q. And it says, "This could happen
2 for at least two reasons," and let's turn the
3 page.
4 The first is the null
5 hypothesis is true, right?
6 A. Uh-huh.
7 Q. And that's what you think is
8 going on in Gustavson, right?
9 A. I think it supports the notion
10 of genetic confounding.
11 Q. And that's the null hypothesis
12 that they're testing there essentially?
13 A. Well, they're testing
14 confounding.
15 Q. Yeah.
16 A. So they're testing the impact
17 of confounding on the prior association in
18 the full cohort.
19 Q. But the second possibility is
20 "the null is false, but by chance, the data
21 happened to be of the kind expected under the
22 null."
23 Did I read that correctly?
24 A. You did.
25 Q. And do you agree that is a

Page 439

1 possibility when study power is low?
2 A. I agree that it's a possibility
3 when study power is low.
4 I think it's unlikely when you
5 demonstrate such a significant decrease in
6 the prior reported measure of association and
7 it attenuates to the null with a small sample
8 size that that possibility is likely.
9 Q. Then it says, "When a study
10 with low power fails to show a significant
11 effect," that's what happened in Gustavson,
12 right?
13 MR. MURDICA: Object to the
14 form.
15 THE WITNESS: So, again, the
16 sibling analysis is embedded within
17 the overall analysis. The sibling --
18 the study itself does not have low
19 power.
20 It's like you're stratifying.
21 If you think about it as stratifying,
22 you're stratifying on the basis of
23 genetics.
24 So the overall power of the
25 study is the overall power of the

Page 440

1 study, and the sibling design is the
2 stratification within that analysis.
3 QUESTIONS BY MR. SNIDOW:
4 Q. Do you see where it says, "The
5 results may, therefore, be more fairly
6 described as inconclusive than negative"?
7 A. I see that.
8 Q. All right. Do you agree with
9 the statement that I've underlined here from
10 the reference manual?
11 MR. MURDICA: Objection --
12 objection to form.
13 THE WITNESS: So, first of all,
14 I don't know what this reference
15 manual is. I don't know who wrote it.
16 I don't know how it's used, and so I'm
17 not going to agree or disagree with
18 the statement that you've pulled out
19 of it because I have no knowledge of
20 its derivation.
21 QUESTIONS BY MR. SNIDOW:
22 Q. Okay. Do you agree when a
23 study with low power fails to show a
24 significant effect, the results may be more
25 fairly described as inconclusive than

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1 negative?
2 Do you agree with that?
3 A. Again, you're asking me to
4 agree with a statement that I have no
5 knowledge of its purpose, its origin, who
6 wrote it. I'm not willing to opine about
7 random statements from manuals that I know
8 nothing about.
9 Q. Okay. Can I ask you, you're a
10 professor of epidemiology, right?
11 A. I am.
12 Q. And you all the time give your
13 opinion about the basics of epidemiological
14 technique, right?
15 A. I do, but that's not what I was
16 asked --
17 Q. No, I know. I know.
18 A. -- to do here.
19 Q. I know.
20 A. And I'm not going to do it
21 here. I think that textbooks can differ,
22 manuals can differ, and I was here to -- I
23 was asked here to evaluate the published
24 epidemiologic literature, and I'm going to
25 stay in that lane.

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1 Q. And you're telling me that in
2 order to tell me whether this basic principle
3 of epidemiology is true or false, you need to
4 know who wrote it?

5 MR. MURDICA: Objection to the
6 form.

7 THE WITNESS: I'm saying that
8 my assignment here, if you will, was
9 not to opine on statements about
10 statistical significance and study
11 power.

12 My assignment was to review the
13 published epidemiologic literature,
14 and I'm just going to stay there.
15 This is not something I've ever seen
16 before.

17 It's not -- I'm not opining as
18 Jennifer Pinto-Martin, professor of
19 epidemiology. I'm opining as an
20 expert witness based on my review of
21 the published literature, and that's
22 what I am -- I'm here to talk about.

23 QUESTIONS BY MR. SNIDOW:
24 Q. Well, this isn't -- this isn't
25 about APAP, right? This is -- this is about

Page 443

1 epidemiology. Can --
2 A. I recognize that.

3 Q. Can you answer the question?
4 Is this -- is this true, or is this not true?
5 Do you know?
6 A. I --
7 Q. Do you know if it's true or
8 not?

9 MR. MURDICA: Objection.
10 Objection to the form. Same
11 objection.

12 THE WITNESS: Again, I'm not
13 going to offer an opinion on a
14 statement that was pulled randomly
15 from a manual that I've never seen
16 before, and it's not my assignment.

17 QUESTIONS BY MR. SNIDOW:
18 Q. Why does it matter who wrote
19 it, like, truly? Why does it matter who
20 wrote that?

21 What if a student came up to
22 you and said, Dr. Pinto-Martin, when a study
23 with low power fails to show a significant
24 effect, the results may therefore be more
25 fairly described as inclusive than negative,

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1 am I right or wrong, what would you tell
2 them?

3 MR. MURDICA: Objection to
4 form.

5 THE WITNESS: Again,
6 hypothetical, I'm not going to respond
7 to what I might say to a student in a
8 different situation. That is not my
9 role here.

10 QUESTIONS BY MR. SNIDOW:
11 Q. Right.
12 A. I'm not here as a professor of
13 epidemiology. I'm here as an expert witness
14 to review the published literature.

15 Q. Well, you're here as an expert
16 in epidemiology, right?
17 A. I'm here as an expert
18 epidemiologist who was asked to review the
19 published literature.

20 (Pinto-Martin Exhibit 627
21 marked for identification.)
22 MR. SNIDOW: Could I have --
23 oh, yeah.

24 QUESTIONS BY MR. SNIDOW:
25 Q. Okay. All right. Doctor, this

Page 445

1 is what you've been wanting to do all day.
2 We're going to look at Gustavson together.

3 MR. MURDICA: Objection to the
4 commentary.

5 MR. SNIDOW: Harmless.

6 QUESTIONS BY MR. SNIDOW:
7 Q. 627.
8 All right. How would you
9 characterize the statistical power of the
10 main analysis, the non-sibling one, in
11 Gustavson?

12 A. It's a very large cohort, and I
13 think that statistical power is one important
14 consideration in evaluating the integrity of
15 the result that they present.

16 Q. High? Medium? Low?
17 MR. MURDICA: Objection. Form.

18 THE WITNESS: It's not a way
19 that I typically evaluate statistical
20 power, but it's a large study, as I
21 said, and I think they had sufficient
22 power to test the association that
23 they were testing.

24 QUESTIONS BY MR. SNIDOW:
25 Q. Let's go to page 7.

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1 It looks like in the main
 2 analysis, the number of children not exposed
 3 to acetaminophen was 12,080?
 4 A. Uh-huh.
 5 Q. And you see that's what they're
 6 using as their control?
 7 A. Yeah. It has the reference.
 8 Yeah.
 9 Q. Yeah, the reference.
 10 And then for acetaminophen,
 11 29 days or more, it's 469?
 12 A. Correct.
 13 Q. So lower, but still pretty big,
 14 right?
 15 A. It's 469.
 16 Q. Yeah.
 17 And they report an unadjusted
 18 and adjusted result. The unadjusted is 2.47;
 19 the adjusted is 2.02?
 20 A. That's correct, that's what
 21 they state in this table.
 22 Q. That corresponds to a doubling
 23 of the risk?
 24 A. That is correct.
 25 Q. Or 100 percent increase in

Page 447

1 risk?
 2 A. That's what a twofold increase
 3 means, yes.
 4 Q. And so I made a little diagram
 5 that I hope will illustrate this.
 6 So this is the Gustavson
 7 primary analysis, right?
 8 They looked at children not
 9 exposed to APAP. There were about 12,000 of
 10 them.
 11 A. Uh-huh.
 12 Q. Is that true? You gave me an
 13 "uh-huh."
 14 Is that true?
 15 A. That's true, uh-huh, so --
 16 Q. Sorry, have to do that.
 17 And then they looked at kids
 18 who were exposed to APAP for more than
 19 29 days?
 20 A. That's correct.
 21 Q. And there were 469. And if you
 22 see here, I -- each one of these is going to
 23 represent 25 children.
 24 A. Oh, I see. Okay.
 25 Q. Okay?

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1 A. Got it.
 2 Q. That's the setup for the
 3 Gustavson paper. It's a cohort study --
 4 A. Uh-huh.
 5 Q. -- prospective?
 6 A. Prospective, although as I
 7 pointed out repeatedly, the assessment of
 8 exposure was actually retrospective because
 9 they were asking women during their pregnancy
 10 to recall exposure from the prior at least
 11 three months.
 12 Q. Right.
 13 But it wasn't retrospective
 14 after they learned whether or not they were
 15 going to experience the outcome, right?
 16 A. They did not know the child's
 17 outcome at the time of assessment of
 18 exposure, correct.
 19 Q. And for recall bias, that's
 20 typically what you're concerned about?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: It's one reason
 24 that recall bias can be introduced.
 25 There are many other reasons,

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1 including, as I pointed out, the
 2 underlying psychological profile of
 3 the mother because we know that women
 4 with anxiety are more likely to
 5 remember negative events and report
 6 negative events.
 7 QUESTIONS BY MR. SNIDOW:
 8 Q. Yeah.
 9 Well, let me ask you and --
 10 while she's getting it. For the Gustavson
 11 paper, you agree only discordant siblings
 12 contribute with information in the sibling
 13 design?
 14 A. That's correct.
 15 Discordant on both.
 16 Q. On both.
 17 A. Doubly discordant, as we say.
 18 Q. What did you say?
 19 A. Doubly discordant.
 20 (Pinto-Martin Exhibit 628
 21 marked for identification.)
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. Okay. I'm going to mark this
 24 as the Gustavson appendix. My tabs have
 25 disappeared yet again.

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1 MR. SNIDOW: What are we up to?

2 MS. BARRIERE: I'm checking.

3 628.

4 MR. SNIDOW: Okay. Thanks.

5 QUESTIONS BY MR. SNIDOW:

6 Q. This is the Gustavson

7 supporting information. You've read this,

8 right?

9 A. I have.

10 Q. And if you look at page 7, it

11 says, "Only discordant siblings contribute

12 with information in the sibling design."

13 True?

14 A. Correct.

15 Q. It says, "380 mothers

16 participated with children discordant on the

17 exposure for 29 days or more."

18 Right?

19 A. Sorry, you must have jumped.

20 300 -- okay.

21 Q. Yeah, I did. "380 mothers

22 participated with children discordant on the

23 exposure for 29 days or more."

24 A. Uh-huh.

25 Q. "34 of them have children

Page 451

1 discordant on the outcome."

2 A. Right.

3 Q. And then it looks like some of

4 them have two, and then some of them have

5 three?

6 A. Uh-huh. I think we end up with

7 38 or 39 by my calculation.

8 Q. Okay.

9 A. But then, of course, you need

10 to double that.

11 Q. Right. Exactly.

12 A. Right?

13 Q. I was going to say, I went

14 through this myself. I think -- I'm not

15 100 percent sure, but I think you'll agree

16 with me that this is what the sample size

17 looks like for the Gustavson sibling control

18 because discordant on exposure was around

19 800 kids because 380 mothers.

20 MR. MURDICA: Objection to

21 form.

22 QUESTIONS BY MR. SNIDOW:

23 Q. And discordant on ADHD

24 diagnosis, I said about 72 because it looks

25 like 36 times 2?

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1 MR. MURDICA: Objection to form

2 and use of demonstrative.

3 THE WITNESS: So I'm sorry, but

4 I believe that the 380 captures the

5 discordance, so I don't think you need

6 to double it.

7 QUESTIONS BY MR. SNIDOW:

8 Q. So you think actually --

9 A. See, they've already captured

10 the discordance in that statement, so it's --

11 380 are discordant on exposure.

12 Q. Well, it's mothers, isn't it?

13 A. Right.

14 Q. And they have kids. I --

15 that's why I said about --

16 A. No, but you measure it from the

17 mother, right?

18 Q. Oh, okay.

19 A. Because the mom is the one

20 who's exposed. So it's 380.

21 Q. Okay.

22 A. Or I think that's what it is,

23 yeah.

24 Q. So it's smaller, smaller --

25 A. Greater than 29, and then

Page 453

1 you're right about sort of doubling the

2 estimate of the discordant outcome.

3 Q. All right. So you think this

4 is -- this is accurate on sample size for the

5 Gustavson?

6 A. Close enough, yes.

7 Q. Yeah.

8 Agree, this is much smaller

9 than this?

10 A. I agree that the sample size is

11 small. Again, I will say the fact that a

12 small sample was able to so effectively

13 attenuate a prior reported association by the

14 same authors -- so they're disagreeing with

15 their prior finding.

16 They're actually debunking

17 their prior finding, which is a very brave

18 thing to do, but it happens in epidemiology

19 because we want to get it right. We want to

20 get to the truth, so we continue to analyze.

21 That's what they did here, and

22 they were able to show genetics matters.

23 They certainly point out that we want this

24 replicated, but it is a very important

25 finding in this -- in this arc of literature,

Page 454

1 it is a very important finding.

2 Q. Well, they said low sample size

3 was a problem, didn't they?

4 MR. MURDICA: Objection to

5 form.

6 THE WITNESS: They said that --

7 QUESTIONS BY MR. SNIDOW:

8 Q. Didn't they say that?

9 A. Let me quote what they said.

10 "The results highlight the importance of

11 using designs that allow for accounting for

12 unmeasured confounding. As only discordant

13 siblings contribute to information in

14 sibling-control models, even the current very

15 large birth cohort provided limit -- limited

16 statistical power. Hence, the results need

17 to be replicated."

18 So they acknowledged that it

19 was limited statistical power, but they still

20 found an association or an attenuation.

21 Q. Is your testimony they didn't

22 say that the low power was a problem for

23 those sibling controls?

24 MR. MURDICA: Objection to

25 form.

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1 THE WITNESS: I just read you

2 what they said.

3 QUESTIONS BY MR. SNIDOW.

4 Q. Well, let's look at the

5 appendix.

6 A. I'm reading -- I'm -- okay.

7 Q. Yeah. Let's look at the

8 appendix.

9 A. This is exactly what they say

10 in their results.

11 Q. No. No. Hold on. Hold on.

12 Do you see this?

13 A. These numbers show that

14 statistical power to detect within effects

15 was relatively low.

16 Q. You agree?

17 A. But they found an effect.

18 Q. I -- I --

19 A. They're acknowledging that it

20 was low, but they found an effect. And then

21 they're saying, let's replicate this. How

22 interesting.

23 They are calling for exactly

24 what we do in epidemiology. Let's replicate

25 this finding.

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1 Q. Hold on.

2 First of all, they found a null

3 finding for the sibling controls, right? So

4 I don't know what you mean by they found --

5 they found a null finding for the sibling

6 controls.

7 A. So the purpose of the sibling

8 control is to compare it to the main cohort

9 analysis.

10 Q. Yep.

11 A. And they found an attenuation

12 of the effect. That is an effect in my mind.

13 It shows that there is confounding, which is

14 the purpose of doing the sibling-control

15 analysis.

16 Q. But you see here, "The numbers

17 shows the statistical power to detect within

18 effects was relatively low."

19 Did I read that correctly?

20 A. You did.

21 Q. All right. And then they say,

22 "Hence, these results should be interpreted

23 with caution."

24 Right?

25 A. A very -- a very wise thing to

Page 457

1 say.

2 Q. You are not interpreting these

3 results with caution, are you?

4 A. I am.

5 MR. MURDICA: Objection to

6 form.

7 THE WITNESS: I'm saying they

8 are incredibly interesting. They

9 needed to be replicated.

10 Again, think about where they

11 come in the arc of evidence, and this

12 is very important to consider. This

13 is the way epidemiology works.

14 I would love to see these

15 results replicated, and I'm sure if

16 anyone has the cohort to do it, they

17 will do so.

18 QUESTIONS BY MR. SNIDOW:

19 Q. Yep.

20 This is -- when I asked you

21 about ADHD -- I'm sorry. When I asked you

22 about autism and ADHD, you said the

23 sibling-control analysis were powerful

24 evidence for you?

25 MR. MURDICA: Objection to

Page 458

1 form.

2 THE WITNESS: I'm sorry, I

3 was --

4 QUESTIONS BY MR. SNIDOW:

5 Q. Yeah, you were -- when I asked

6 you -- do remember about this?

7 A. Yes.

8 Q. Yeah.

9 A. Well, I said genetics is a

10 powerful --

11 Q. And you said Gustavson --

12 A. -- factor.

13 Q. -- was your -- was your main

14 basis; is that right?

15 A. For ADHD.

16 Q. For ADHD?

17 A. Right. I mean, that's the one

18 that has a sibling control, so that's the

19 only one you can look at.

20 Q. And they said, "Interpret our

21 sibling control results with caution."

22 Right?

23 A. They didn't say ignore them.

24 They said interpret them with caution. This

25 is the first -- "We are the first group to do

Page 459

1 this" --

2 Q. Yes.

3 A. -- and they're putting it out

4 there as a call for others to replicate,

5 which is exactly what they should do.

6 Q. Yeah.

7 So let's look at page 8 of

8 Gustavson.

9 A. Page 8 of Gustavson. Yeah,

10 okay.

11 Q. Do you see, "This may lead to

12 false conclusions that observed associations

13 are due to familial confounding factors"?

14 Did I read that correctly?

15 MR. MURDICA: Objection to

16 form.

17 THE WITNESS: So this -- let's

18 go back and see what "this" is.

19 QUESTIONS BY MR. SNIDOW:

20 Q. Yeah, it's nondifferential

21 misclassification error.

22 MR. MURDICA: Objection to

23 form.

24 It's not a question.

25 THE WITNESS: It says,

Page 460

1 "Measurement error," which could mean

2 lots of things, right? It could mean

3 misclassification by exposure. It

4 could mean imprecision in that

5 exposure estimate.

6 "Measurement error" is a broad

7 term. It's not -- they're not saying

8 misclassification here. They're

9 saying measurement error, and that's

10 something that I pointed out

11 repeatedly. We don't have solid

12 exposure information from any of these

13 data.

14 QUESTIONS BY MR. SNIDOW:

15 Q. But what they're saying here is

16 that could lead to a false conclusion that

17 the observed results are due to familial

18 confounding factors.

19 A. That is what they're saying.

20 Q. Do you agree with that?

21 A. I think it's always a

22 possibility in sibling control, but

23 they're saying -- they have to be honest

24 about what the results might mean. They're

25 not dismissing their results on the basis of

Page 461

1 this. They're acknowledging that it -- that

2 a sibling-control analysis has limitations,

3 which I think is a very honest and

4 straightforward way to do it.

5 And, by the way, did you notice

6 one of the coauthors was the person that you

7 were talking about earlier as a very renowned

8 epidemiologist, the former department chair

9 at Columbia, Ezra Susser, who I have great

10 respect for.

11 I just point that out.

12 Q. So where in the Gustavson paper

13 does it ever say, we have proven that these

14 associations are the result of residual

15 confounding?

16 MR. MURDICA: Objection to

17 form.

18 THE WITNESS: So no credible

19 epidemiologist would say they had

20 proven anything on the basis of a

21 single study.

22 What we do is analyze the data,

23 put the data forth as evidence in

24 support of the null hypothesis or in

25 support of a research hypothesis and

Page 462

1 then call for confirmation of the
2 finding.

3 And I think they were, again --
4 they showed a lot of integrity in the
5 way that they presented their results.

6 QUESTIONS BY MR. SNIDOW:

7 Q. So that's a, no, they didn't
8 say that.

9 MR. MURDICA: Objection to
10 form.

11 THE WITNESS: I think I
12 answered the question.

13 QUESTIONS BY MR. SNIDOW:

14 Q. Okay. Did they ever say, now
15 that we have our sibling-control results, we
16 know that the association between APAP and
17 ADHD is a spurious one? Did they say that?

18 A. What they said was it points to
19 evidence of confounding by genetics, and they
20 called out for replication of the finding.

21 Again, that's precisely what I
22 would expect an epidemiologist with integrity
23 to do based on a single study.

24 Q. Let's look at the actual
25 results of Gustavson and see how compelling

Page 463

1 they actually are.

2 So this is the table that they
3 report?

4 A. Uh-huh.

5 Q. And this is the main result,
6 right?

7 A. That is the result from the
8 entire cohort.

9 Q. Yeah.

10 A. The model that was presented in
11 Ystrom.

12 Q. And this is the sibling-control
13 result that you like?

14 MR. MURDICA: Objection to
15 form.

16 THE WITNESS: This is the
17 result of the sibling-control analysis
18 showing that the prior result is
19 attenuated towards the null. You can
20 see that the point estimate is down at
21 1, and it has a confidence interval
22 that goes way below 1 and way above 1.

23 QUESTIONS BY MR. SNIDOW:

24 Q. It's actually 1.06, right?

25 A. I don't recall precisely, but

Page 464

1 that sounds right.

2 Q. So even in Gustavson, the child
3 that was exposed to APAP in utero had a 6 --
4 the point estimate was a 6 percent higher
5 risk of getting ADHD than his nonexposed --
6 his or her nonexposed sibling, right?

7 MR. MURDICA: Objection to
8 form.

9 THE WITNESS: I don't think
10 that's the way to interpret a sibling
11 analysis. Because what a sibling
12 analysis is designed to do is
13 demonstrate the effect of genetic
14 confounding. And so the result is the
15 attenuation, the extent of
16 attenuation, towards the null, which
17 is very substantial, and the lack of
18 statistical significance is also
19 relevant here.

20 QUESTIONS BY MR. SNIDOW:

21 Q. Yeah. But I'm going to need an
22 answer on this.

23 The actual results of the
24 sibling control, the actual point estimate
25 they got, showed that the exposed child had a

Page 465

1 6 percent higher likelihood of developing
2 ADHD than the nonexposed sibling. That's
3 what happened.

4 MR. MURDICA: Objection to
5 form.

6 THE WITNESS: It's a not --
7 it's a nonsignificant finding, so I
8 would never be willing to say that it
9 illustrates a 6 percent increased
10 risk.

11 It's -- it could have
12 illustrated a result that is
13 protective. It could have illustrated
14 a result that was higher than that.
15 So the point estimate is meaningless
16 when you have wide confidence
17 intervals and it's not significant.

18 QUESTIONS BY MR. SNIDOW:

19 Q. Exactly.

20 So it goes all the way up to,
21 like, 2, right?

22 MR. MURDICA: Which one are you
23 talking about now?

24 MR. SNIDOW: This one. It goes
25 all the way up to 2.

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1 THE WITNESS: He's talking
2 about more than 29 days, sibling
3 control.
4 So the attenuation is towards
5 the null, and the confidence intervals
6 are wide, granted. But as I said, the
7 interpretation is how does the
8 sibling-controlled analysis -- this
9 is -- this is the way you run the
10 analysis, right. How does the
11 sibling-control analysis compare to
12 the full cohort analysis. And if we
13 see that reduction in risk, it
14 identifies genetics as a confounder.
15 Does it prove that this is all
16 about genetics? No. And that's why
17 they're saying, this is a really
18 interesting finding, it shows the
19 impact of genetics on that prior
20 result, and we need more studies to do
21 the same kind of thing.
22 QUESTIONS BY MR. SNIDOW:
23 Q. You think that when there are
24 overlapping confidence intervals that raises
25 the question of whether the values are

Page 467

1 meaningful different, right?
2 A. Sometimes. I -- I've said
3 that, and I do think that sometimes, not
4 always, but there are instances where it's
5 pretty obvious that there's not a difference
6 and someone is trying to describe it as
7 different.
8 Q. This one, though, it's not that
9 obvious, right? These confidence intervals
10 are halfway overlapping, right?
11 A. Again, we're talking about two
12 different analyses, and this is a subset of
13 the prior analysis. So I don't think it's
14 fair to talk about overlapping confidence
15 intervals because we are doing basically a
16 subanalysis, a stratified analysis from the
17 overall cohort.
18 Q. I get that you don't think it's
19 fair, but are these overlapping confidence
20 intervals or not?
21 MR. MURDICA: Objection to
22 form.
23 QUESTIONS BY MR. SNIDOW:
24 Q. Do they overlap?
25 MR. MURDICA: Objection to

Page 468

1 form.
2 THE WITNESS: You've already
3 pointed out that they overlap --
4 QUESTIONS BY MR. SNIDOW:
5 Q. All right.
6 A. -- and I've tried to describe
7 that I think when you're doing a
8 sibling-control analysis, it's a subanalysis
9 of your overall cohort. And comparing the
10 width of the confidence intervals or the
11 overlapping nature of the confidence
12 intervals is not as relevant as it might be
13 in a situation where you weren't doing a
14 subanalysis within your overall cohort.
15 Q. Well, here's maybe why it could
16 be relevant.
17 You can't statistically exclude
18 the possibility that the main result was down
19 here and the sibling-control result was up
20 here, right?
21 MR. MURDICA: Objection to
22 form.
23 QUESTIONS BY MR. SNIDOW:
24 Q. Can you exclude that
25 statistically?

Page 469

1 A. So we know that the farther
2 away you get from the point estimate on the
3 confidence interval, the less likely that
4 result is. I can't determine that looking at
5 it right now, and they didn't try to
6 determine that.
7 What they said was, our
8 sibling-control analysis revealed evidence of
9 confounding by genetics. We think that's
10 important. There are many other people who
11 have talked about the importance of genetic
12 confounding. I would say almost every study
13 that I reviewed said that in their
14 conclusions and limitations, even if they
15 found an effect, well, we need to be cautious
16 in our interpretation because of the
17 possibility of residual confounding by
18 genetics.
19 So here we have a study that's
20 actually able to demonstrate that it does
21 have an impact.
22 Q. It says here, "Third, the
23 sibling-comparison model adjusts not only for
24 stable confounding factors but also for
25 potential mediating factors"?

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1 A. That affect all siblings,
 2 that's correct.
 3 Q. Yeah. You agree?
 4 A. That is something that has been
 5 pointed out about sibling control, and it is
 6 an issue. In order to test for a mediation
 7 effect, you need to have what the mediator
 8 is, a definition of the mediator, and data on
 9 the mediator.
 10 And I have -- I've seen nothing
 11 to support that the sibling-control analysis
 12 in this, or any other study that I've looked
 13 at, can demonstrate the impact of a mediating
 14 effect. It's theoretically possible. It's
 15 not what's happening here.
 16 Q. But the authors call it out
 17 here, right?
 18 A. Again, being honest, they say
 19 they have to note that this is -- you know,
 20 sibling-control analysis is a statistical
 21 technique. It's not perfect, but it has
 22 power in demonstrating the role of unmeasured
 23 confounding.
 24 Q. Do you see here where they do
 25 their conclusions? You see where it says,

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1 "The results suggest that may be at least
 2 partly due to familial confounding"?
 3 A. I do.
 4 Q. Do you think it's all of it?
 5 A. I don't think we can say on the
 6 basis of one study whether it's all of it or
 7 part of it. Again, without knowing what the
 8 components of familial confounding are, what
 9 we see is this has an impact, and we don't
 10 have the underlying data to really parse
 11 that.
 12 Q. So you can't say for sure that
 13 genetic confounding explains the entire
 14 association between prenatal APAP exposure
 15 and autism?
 16 MR. MURDICA: Objection to
 17 form.
 18 THE WITNESS: I don't think
 19 anybody can. Because, again, autism
 20 is not completely heritable, and here
 21 we have a demonstration of a profound
 22 impact when we try to control for that
 23 heritability. But there's -- it's not
 24 a perfect measure, and it's one study.
 25

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1 QUESTIONS BY MR. SNIDOW:
 2 Q. And same question for ADHD.
 3 You can't say for sure that genetic
 4 confounding explains the entire association
 5 between prenatal APAP exposure and ADHD?
 6 MR. MURDICA: Objection to
 7 form.
 8 THE WITNESS: I cannot say that
 9 because we don't have evidence to
 10 support that. I think without, you
 11 know, designing a new study, there
 12 will always be the possibility of
 13 other confounders.
 14 QUESTIONS BY MR. SNIDOW:
 15 Q. And that's -- and that's a
 16 possibility, right?
 17 Genetic confounding could be
 18 partially an explanation for the association,
 19 but there could remain some that's truly
 20 causal?
 21 MR. MURDICA: Objection to
 22 form.
 23 THE WITNESS: In my opinion,
 24 there is no evidence in the published
 25 literature, epidemiologic literature,

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1 to suggest a causal relationship.
 2 There are many reasons for
 3 that. Genetic confounding is one of
 4 them, and all the other reasons we
 5 talked about all day long, which I can
 6 go through again, if you like, are the
 7 other reasons.
 8 MR. SNIDOW: All right. Want
 9 to take a break?
 10 THE WITNESS: Yes.
 11 MR. MURDICA: Sure.
 12 VIDEOGRAPHER: The time is
 13 4:14 p.m., and we're off the record.
 14 (Off the record at 4:14 p.m.)
 15 VIDEOGRAPHER: The time is
 16 4:26 p.m., and we're on the record.
 17 MR. SNIDOW: Just for the
 18 record, based on Dr. Pinto's-Martin --
 19 Pinto-Martin's refusal to answer my
 20 questions about whether statements
 21 about epidemiology in the reference
 22 manual were true or not, we are
 23 reserving the right to reopen the
 24 deposition.
 25 MR. MURDICA: Regarding the

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1 one -- the one sentence you asked
2 about?

3 MR. SNIDOW: That she told me
4 she would not answer because it was
5 not what she was called here to
6 testify about.

7 MR. MURDICA: Okay. Why don't
8 you just call the judge now?

9 MR. WATTS: Come on, guys.
10 Let's go.

11 QUESTIONS BY MR. SNIDOW:
12 Q. All right. Dr. Pinto-Martin,
13 do you agree that the work you do in the
14 field of autism epidemiology relates to
15 possible environmental causes?

16 A. I do.

17 Q. And that's work you do at
18 UPenn?

19 A. That's correct.

20 Q. Part of your job duties at
21 UPenn?

22 A. So it's a grant --

23 Q. Yeah.

24 A. -- right. So it's external
25 funding to support research that is looking

Page 475

1 into the etiology of autism spectrum
2 disorders.

3 Q. And on the Penn website you say
4 that you're a researcher who looks into
5 possible environmental causes of autism?

6 A. That's correct.

7 Q. And you agree that you were
8 retained in this case in part because of your
9 professional standing or expertise in the
10 field of autism research?

11 MR. MURDICA: Objection to
12 form.

13 THE WITNESS: I believe that's
14 true.

15 QUESTIONS BY MR. SNIDOW:
16 Q. In particular, because of your
17 professional standing or expertise in
18 relation to potential environmental causes of
19 autism?

20 MR. MURDICA: Objection to
21 form.

22 THE WITNESS: I don't actually
23 know. I mean, no one said to me, this
24 is why we want to retain you.
25 I think that what you can see

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1 from my life's work, actually, is that
2 I have devoted myself to understanding
3 the etiology of autism spectrum
4 disorders, and that includes potential
5 environmental factors.

6 And, in fact, the SEED study
7 that -- that the CDC has supported for
8 many, many years now is looking at the
9 genetic causes and the causes beyond
10 genetics, I would say. Whatever --
11 however you want to characterize them.

12 QUESTIONS BY MR. SNIDOW:
13 Q. Okay. Do you agree that some
14 of the associations in this literature are
15 strong ones?

16 MR. MURDICA: Objection to the
17 form.

18 THE WITNESS: So "strong" is a
19 word that people use in epidemiology
20 typically to describe the size of the
21 measure of association. And so I ask
22 you what you mean by "strong."

23 QUESTIONS BY MR. SNIDOW:
24 Q. You have a section in your
25 report on strength. Okay?

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1 So you have some idea of what
2 you mean by strong or weak associations,
3 right?

4 A. I do.

5 Q. Okay. So use that one, and
6 tell me if some of the associations in the
7 literature are strong.

8 A. So I would say that none of the
9 associations in the literature are strong.

10 Q. All right.

11 A. Because although some of them
12 report a measure of association that is some
13 might say substantially above 1, the data
14 supporting that measure of association is
15 flawed and, therefore, I can't describe it as
16 a strong association.

17 (Pinto-Martin Exhibit 629
18 marked for identification.)

19 QUESTIONS BY MR. SNIDOW:
20 Q. I'm going to show you a
21 document that I'm going to mark as --
22 COURT REPORTER: 629.

23 MR. SNIDOW: Thank you.

24 QUESTIONS BY MR. SNIDOW:
25 Q. 629. It's the Ji 2020 paper.

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1 A. This one? Okay.

2 Q. Have you seen this one?

3 A. I have.

4 Q. And if you turn to page 186.

5 A. Uh-huh.

6 Q. They report the results, right?

7 A. They do.

8 Q. And you see for cord

9 acetaminophen burden -- and that's their

10 composite dataset?

11 A. Uh-huh.

12 Q. They report the results for

13 ADHD?

14 A. They do.

15 Q. And for ASD?

16 A. Correct.

17 Q. The results for ADHD in the

18 first -- excuse me, the second tertile is

19 2.26?

20 A. That's what they report.

21 Q. As compared to the first?

22 A. That's correct.

23 Q. 2.86 for the third?

24 A. That's correct.

25 Q. And those results are

Page 479

1 statistically significant?

2 A. They are significant, correct.

3 Q. That means less than 5 percent

4 likelihood of being a chance finding there,

5 right?

6 MR. MURDICA: Objection to

7 form.

8 THE WITNESS: That's the

9 definition of statistical

10 significance, yes.

11 QUESTIONS BY MR. SNIDOW:

12 Q. For ASD, they report the odds

13 ratio at 2.14?

14 A. For the second tertile, the

15 odds ratio is 2.14, not statistically

16 significant.

17 Q. 3.62 for the third?

18 A. Correct.

19 Q. And that one is?

20 A. And that one is statistically

21 significant, yes.

22 Q. All right. Let's look at what

23 that looks like.

24 So here is the results for Ji,

25 right?

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1 MR. MURDICA: Objection to form

2 and demonstrative.

3 THE WITNESS: So we have the

4 first tertile. Clue me into your

5 little diagram here.

6 So we have -- how many people

7 do each -- does each little person

8 represent on this one?

9 QUESTIONS BY MR. SNIDOW:

10 Q. It's in percent. So I've got

11 100 them.

12 A. Okay.

13 Q. And I've done percent. If you

14 want to look --

15 A. No, it's okay.

16 Q. Yeah.

17 A. I just wanted to understand it.

18 Q. Yeah.

19 A. Okay. This is for ADHD, okay.

20 Q. And can you look at the cord

21 acetaminophen burden table and tell me if I

22 got this right?

23 A. We just went over the numbers,

24 so, yes, you --

25 MR. MURDICA: Objection to the

Page 481

1 form and to the demonstrative that he

2 created.

3 QUESTIONS BY MR. SNIDOW:

4 Q. It's -- did you say, Yeah, I

5 got it right?

6 A. We just looked at those

7 numbers, and these are consistent with what

8 we just looked at.

9 Q. Yes.

10 MR. MURDICA: The doctor -- let

11 the record reflect the doctor is

12 looking at Exhibit 629, not whatever

13 plaintiff's counsel created.

14 QUESTIONS BY MR. SNIDOW:

15 Q. Are you -- are you looking at

16 this?

17 A. I'm looking at both.

18 Q. Okay. Good. I just wanted to

19 make sure. Mr. Murdica suggested otherwise.

20 But -- so the second tertile

21 here, a lot more kids got ADHD, would you

22 agree?

23 MR. MURDICA: Objection to

24 form.

25 THE WITNESS: A lot more kids

Page 482

1 is a pretty imprecise statement.

2 QUESTIONS BY MR. SNIDOW:

3 Q. All right. Well --

4 A. We can look at the exact number

5 if we wanted to do that.

6 Q. More than a doubling of the

7 risk?

8 A. It's more than a doubling of

9 the risk, correct.

10 Q. And third tertile, 2.86?

11 A. Correct.

12 Q. That's more than doubling of

13 the risk?

14 A. That's correct.

15 Q. All right. And the results

16 here I'm reporting, those are adjusted

17 results, true?

18 MR. MURDICA: Objection to

19 form.

20 THE WITNESS: Those are

21 adjusted by a set of potential

22 confounders that include maternal age,

23 race, ethnicity, education, marital

24 status, stress during pregnancy,

25 smoking before or during, alcohol

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1 before or during, maternal body mass

2 index, parity, child sex, delivery

3 type, preterm birth and low birth

4 weight. Notably not genetics.

5 QUESTIONS BY MR. SNIDOW:

6 Q. Well, it's -- you can't just

7 adjust for genetics, right? It's hard to

8 measure.

9 A. Well, you could do a stratified

10 analysis on --

11 Q. You can do things that are

12 correlated with genetics, right?

13 A. That's what we've talked about.

14 Q. And sex is highly correlated

15 with genetics?

16 A. It's determined by genetics.

17 Q. I agree.

18 Same thing with race, although

19 obviously less than sex?

20 A. (Witness nods head.)

21 Q. Is that right?

22 MR. MURDICA: Objection to

23 form.

24 THE WITNESS: I'm not sure the

25 point of your question.

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1 QUESTIONS BY MR. SNIDOW:

2 Q. No, I'm just --

3 A. But, yes, that's true.

4 Q. My point is just that race

5 is obviously correlated with genetics, right?

6 A. I would agree with that

7 statement.

8 Q. And those were controlled in

9 this study?

10 A. Those were controlled in that

11 study.

12 Q. And did you notice in my -- in

13 my diagram, I'm reporting essentially the

14 crude risk ratios, right? Because I'm just

15 showing the percentage of kids?

16 MR. MURDICA: Objection. Form.

17 THE WITNESS: You just told me

18 you reported the adjusted, and that's

19 what we are seeing here in this table.

20 QUESTIONS BY MR. SNIDOW:

21 Q. Well --

22 A. Cord acetaminophen --

23 Q. Well, I was actually trying to

24 have you look at the percentages.

25 So you see the percentages.

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1 Remember I said I'm reporting percentages?

2 A. Well, you're showing the

3 percentages with your little people.

4 Q. Uh-huh.

5 A. And you're reporting the

6 relative risk that they report in their

7 paper, which is what we do, right? We

8 calculate the incidence in the exposed

9 compared to the incidence in the unexposed,

10 and that is how we get relative risk.

11 Q. Absolutely.

12 And so if I wanted to do the

13 crude relative risk, I divide incidence here

14 divided by here, right?

15 A. So --

16 MR. MURDICA: Objection to

17 form.

18 THE WITNESS: So I wouldn't

19 call it incidence because we don't

20 know that these are incident cases.

21 These are prevalent cases.

22 So we would look at the number

23 of individuals with autism in one

24 tertile compared to the reference

25 tertile.

<p style="text-align: right;">Page 486</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Yep.</p> <p>3 Okay. What's it mean when you</p> <p>4 adjust for confounders and the association</p> <p>5 goes up versus the crude?</p> <p>6 A. Very good question and very</p> <p>7 hard to interpret. We don't really know what</p> <p>8 that means. I mean, I think that it shows</p> <p>9 that there is something that we don't</p> <p>10 understand about the causal pathway is --</p> <p>11 would be my first interpretation.</p> <p>12 But it's a -- it's a</p> <p>13 challenging question that a lot of people</p> <p>14 have thought about, and I don't think there's</p> <p>15 a perfect answer for it.</p> <p>16 Q. Okay. If we look at the chart</p> <p>17 for autism, you agree this is -- these are</p> <p>18 the results?</p> <p>19 MR. MURDICA: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: These are the</p> <p>22 results they report in Table 2,</p> <p>23 "adjusted associations between cord</p> <p>24 plasma acetaminophen biomarkers and</p> <p>25 the risk of physician-diagnosed</p>	<p style="text-align: right;">Page 488</p> <p>1 A. The results indicate an</p> <p>2 increased risk among those who have cord</p> <p>3 acetaminophen measured right at the time of</p> <p>4 delivery, which is not relevant to fetal</p> <p>5 brain development throughout the trimesters.</p> <p>6 So I question the value, I</p> <p>7 would say, of the results --</p> <p>8 Q. Well --</p> <p>9 A. -- with respect to informing my</p> <p>10 opinion about prenatal acetaminophen exposure</p> <p>11 and risk of ASD or ADHD.</p> <p>12 Q. Well, the study authors didn't</p> <p>13 say it was worthless, right?</p> <p>14 They said, "Our findings</p> <p>15 support previous studies regarding the</p> <p>16 association between prenatal and perinatal</p> <p>17 acetaminophen exposures and childhood</p> <p>18 neurodevelopmental risk"?</p> <p>19 A. I mean, study authors rarely</p> <p>20 say that their findings are inconsequential.</p> <p>21 Q. Right. I know.</p> <p>22 A. I think they elsewhere talk</p> <p>23 about the notion that this is a point in time</p> <p>24 measurement and may not reflect anything</p> <p>25 other than perinatal exposure.</p>
<p style="text-align: right;">Page 487</p> <p>1 conditions."</p> <p>2 In this case, we're looking at</p> <p>3 ASD, and we looked before at ADHD.</p> <p>4 I will say that the exposure</p> <p>5 information they're relying on here,</p> <p>6 cord acetaminophen burden and then</p> <p>7 various markers within that cord</p> <p>8 acetaminophen, is a point in time</p> <p>9 measurement that really only reflects</p> <p>10 exposure right around the time of</p> <p>11 delivery, and actually, perhaps,</p> <p>12 post-delivery for women who may have</p> <p>13 pain from a C-section or something</p> <p>14 like that.</p> <p>15 So I think that it's important</p> <p>16 to point out what the tertiles</p> <p>17 reflect.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. All right. But these are the</p> <p>20 actual results?</p> <p>21 A. These are the results reported</p> <p>22 in Table 2.</p> <p>23 Q. All right. So kids who had</p> <p>24 more acetaminophen in their cord blood got</p> <p>25 more ASD than the ones who had less, right?</p>	<p style="text-align: right;">Page 489</p> <p>1 Q. And that's a limitation, just</p> <p>2 like we saw in the Gustavson paper, right?</p> <p>3 MR. MURDICA: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: It's a rather --</p> <p>6 it's a rather huge limitation in my</p> <p>7 mind when you're talking about fetal</p> <p>8 brain development, which starts very</p> <p>9 early on and continues throughout</p> <p>10 pregnancy.</p> <p>11 And here we have an exposure</p> <p>12 that happened right at the end, and</p> <p>13 we're trying to link that to a</p> <p>14 diagnostic outcome.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. All right. They say, "The</p> <p>17 dose-response associations found for the</p> <p>18 current study also addressed the methodologic</p> <p>19 issues identified by the Society for</p> <p>20 Maternal -- Maternal-Fetal Medicine, FDA and</p> <p>21 American Association of Pediatrics regarding</p> <p>22 the reliance on maternal self-reported</p> <p>23 acetaminophen exposures in previous cohort</p> <p>24 studies."</p> <p>25 Right?</p>

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1 A. That's what they say.

2 Q. Right.

3 A. And I'm not sure I agree with

4 that because the fact that they are relying

5 on a biological marker may at first blush

6 seem like a better approach to measuring

7 exposure.

8 But if you think carefully

9 about how fetal brain development works and

10 how exposure in terms of dose and timing and

11 duration might impact that, we have almost no

12 information from this study on that.

13 Q. You see here they say,

14 "Reliance on maternal self-reported"?

15 A. I see that.

16 Q. That's what you've been telling

17 me about for a good amount of the day, right?

18 A. That is --

19 MR. MURDICA: Objection to

20 form.

21 THE WITNESS: So maternal

22 self-report is not a perfect

23 measurement either.

24 QUESTIONS BY MR. SNIDOW:

25 Q. Yeah.

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1 A. What I'm saying is that these

2 results, you pointed them out as the

3 strongest results or big numbers.

4 And I'm just saying that they

5 don't inform my opinion about prenatal use

6 because I would say this is peripartum

7 exposure and not prenatal.

8 Q. So you disagree with the

9 authors' interpretation of their study,

10 right?

11 A. I do.

12 Q. Or -- is that a "yes"?

13 A. I do.

14 Q. All right. They say they were

15 dose-response patterns.

16 You disagree?

17 MR. MURDICA: Objection to

18 form.

19 THE WITNESS: So I think that

20 they have established that there's a

21 dose-response by the biomarkers that

22 they measure.

23 However, I don't know how those

24 biomarkers related to fetal brain

25 development, much less to the ultimate

Page 492

1 diagnosis of ASD or ADHD.

2 QUESTIONS BY MR. SNIDOW:

3 Q. Right.

4 Because no question, this is a

5 dose-response, right?

6 MR. MURDICA: Objection to

7 form.

8 THE WITNESS: Again, the

9 biomarkers show an increased risk as

10 the level of that biomarker goes up,

11 but it was taken at the time of

12 delivery and does not relate to fetal

13 brain development, in my opinion.

14 QUESTIONS BY MR. SNIDOW:

15 Q. And, yeah. If you disagree,

16 we'll just put it -- can I have Baker? Yep.

17 Nope. Yeah.

18 All right. Did you review the

19 Baker study?

20 A. I did.

21 Q. That one's about meconium?

22 A. Correct.

23 Q. And do you agree that the

24 results in that were fairly strong?

25 MR. MURDICA: Objection to

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1 form.

2 THE WITNESS: I do not.

3 QUESTIONS BY MR. SNIDOW:

4 Q. All right. Well, while she's

5 getting that, let me do one more thing.

6 Here's the secondhand smoke

7 result. Do you remember that one?

8 A. I do.

9 Q. And here's the Baker result.

10 Do you see that?

11 A. I see that you've made a

12 graphic of probably what comes from one of

13 the tables.

14 Q. Yes.

15 A. So...

16 Q. So can you tell me which is a

17 stronger association, this or this?

18 MR. MURDICA: Objection to form

19 and the use of these graphics you

20 created.

21 QUESTIONS BY MR. SNIDOW:

22 Q. Can you tell me that?

23 A. I can't tell you that because

24 context matters.

25 Q. Yeah. That's fine.

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1 The number's a lot smaller,
2 though, right? This one is 1.3, and this one
3 is 3?
4 MR. MURDICA: Objection to
5 form.
6 THE WITNESS: As I've said
7 repeatedly, it's not just about the
8 numbers.
9 QUESTIONS BY MR. SNIDOW:
10 Q. And can you give me a citation
11 for that, that when you're looking for
12 strength in Bradford Hill, you need to look
13 at the underlying data and not just the
14 magnitude of the association?
15 A. I can't cite you something
16 specific to that, but I think it's a common
17 belief among thoughtful epidemiologists that
18 context is incredibly important.
19 Q. I know context is important,
20 but we're doing strength.
21 Can you cite anything that
22 says, you know, don't just look at the
23 magnitude of the point estimate, you need to
24 actually go and look at all of the data
25 underlying all the studies?

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1 A. Again, I just think it's common
2 sense. I don't look at things in isolation,
3 so it's the way I approach things, and I'm
4 not alone in that.
5 (Pinto-Martin Exhibit 630
6 marked for identification.)
7 QUESTIONS BY MR. SNIDOW:
8 Q. All right. Here is Baker,
9 which Christy {sic} is going to tell me what
10 to mark as.
11 A. 630, I think, right?
12 Q. Great. Here's Baker.
13 And do you see here they say,
14 "A dose-response association was detected.
15 Each doubling of exposure increased the odds
16 of ADHD by 10 percent."
17 Do you see that?
18 A. I do see that.
19 Q. Do you agree that they detected
20 a dose-response association here?
21 MR. MURDICA: Objection to
22 form.
23 THE WITNESS: So the analytes
24 from the meconium appear to increase
25 the risk of the odds of ADHD.

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1 However, similar to the Ji
2 study, I take exception to using a
3 biomarker that is collected after
4 delivery to reflect exposure
5 throughout pregnancy.
6 Although we know that meconium
7 does develop throughout pregnancy, we
8 also know that babies don't poop, to
9 be straightforward about it, until
10 several days, sometimes, after
11 delivery, and we know -- I'll just
12 tell you because my mother -- my
13 mother -- my daughter just had a baby,
14 and she had a C-section, and so she
15 was taking a lot of Tylenol after
16 birth, and she was also nursing her
17 baby.
18 And so I am quite sure that any
19 acetaminophen that might have been
20 detected in Teddy's poop could have
21 been a function of the exposure she
22 had during delivery, after delivery
23 and through the breast milk.
24 QUESTIONS BY MR. SNIDOW:
25 Q. Right.

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1 Do you -- are you an expert in
2 how exposures get into meconium at which
3 points in pregnancy?
4 MR. MURDICA: Objection to
5 form.
6 THE WITNESS: I'm not an expert
7 in how exposures get into meconium
8 during pregnancy, but I have read that
9 exposures accumulate in meconium
10 throughout pregnancy.
11 We have no information from
12 Baker about how the exposure measured
13 in the meconium relates to maternal
14 usage throughout pregnancy.
15 QUESTIONS BY MR. SNIDOW:
16 Q. You see here, though, the
17 conclusions they said, "By using a direct
18 measurement of prenatal acetaminophen
19 exposure that's unbiased by maternal recall."
20 Do you see that?
21 A. I do see that. And that's --
22 Q. Do you agree the measure was
23 unbiased by maternal recall?
24 A. The measure is unbiased by
25 maternal recall. That does not equate with

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1 demonstration of an increased risk of APAP in
 2 the meconium and ADHD or ASD.
 3 Q. They seem to disagree. Because
 4 they said, "These results add evidence in
 5 support of the association between prenatal
 6 acetaminophen use and child ADHD."
 7 Right?
 8 MR. MURDICA: Objection to
 9 form.
 10 THE WITNESS: That is their
 11 statement.
 12 QUESTIONS BY MR. SNIDOW:
 13 Q. Do you disagree with the study
 14 authors again?
 15 A. I disagree with the study
 16 authors again.
 17 Q. How many do you think you've
 18 disagreed with today? Do you think it's more
 19 than five?
 20 MR. MURDICA: Objection to the
 21 form.
 22 THE WITNESS: I didn't count.
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Well, what do you think is
 25 going on here? Why are all these

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1 researchers, who are doing this in their day
 2 job, getting all of this stuff wrong? Do you
 3 have an explanation for that?
 4 MR. MURDICA: Objection to the
 5 form.
 6 THE WITNESS: So I don't think
 7 it's a question of getting things
 8 wrong. I think these are people who
 9 are trying their best to understand
 10 whether there is a true causal
 11 association between prenatal APAP use
 12 and higher risk of an adverse
 13 neurodevelopmental outcome in the
 14 offspring.
 15 Most epidemiologists, and I
 16 would put myself among them, care
 17 deeply about finding the truth. And
 18 so these are people who are doing
 19 their best with, as we've discussed,
 20 flawed data --
 21 MS. BARRIERE: He's reading
 22 what you're saying at the same time.
 23 MR. SNIDOW: Oh, yeah. Sorry
 24 about that. I got your transcript
 25 here.

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1 MS. BARRIERE: He's not
 2 ignoring you.
 3 MR. SNIDOW: I've got to read
 4 what you're saying.
 5 THE WITNESS: Okay. It's just
 6 very distracting to have you poking
 7 her and --
 8 MR. SNIDOW: I couldn't -- I
 9 couldn't -- I couldn't see.
 10 MS. BARRIERE: Sorry.
 11 THE WITNESS: Okay. It's
 12 just -- I'm sorry. It's just
 13 distracting.
 14 MR. SNIDOW: It's okay.
 15 THE WITNESS: It feels
 16 disrespectful.
 17 MS. BARRIERE: It wasn't
 18 intended.
 19 MR. SNIDOW: It's really not.
 20 This is -- this is your transcript. I
 21 obviously have to read it. I can't
 22 look you in the eye and do that at the
 23 same time. I think you understand.
 24 THE WITNESS: I didn't know
 25 that that's what you were doing.

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1 Thank you for explaining it.
 2 QUESTIONS BY MR. SNIDOW:
 3 Q. Yes. All right.
 4 You want me to ask you the
 5 question again?
 6 A. Yes, please.
 7 Q. The people who keep saying, you
 8 know, we think this is -- this is causation,
 9 we don't think this is confounding and so on,
 10 what do you think is going on there?
 11 MR. MURDICA: Objection to the
 12 form.
 13 THE WITNESS: So what I think
 14 is going on is that epidemiologists
 15 who have data that might be relevant
 16 to the very important question of
 17 whether prenatal APAP exposure
 18 increases the risk of diagnostic ASD
 19 or ADHD are analyzing that data to the
 20 best of their ability and putting that
 21 information forth in the published
 22 literature.
 23 And that has been going on for
 24 about ten years now pretty steadily,
 25 and the data is in toto not convincing

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1 because there are so many flaws.
 2 It's a very, very difficult
 3 study to perform, in large part,
 4 because the exposure, which has to be
 5 precise with respect to timing and
 6 dose and duration, if we really want
 7 to know what its impact is on fetal
 8 brain development, is simply not
 9 there.
 10 And these are two authors
 11 who've attempted to use a biological
 12 marker, but the biological marker
 13 itself has flaws with respect to
 14 interpreting timing, dose and
 15 duration.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. But you're not saying those
 18 authors are acting in bad faith?
 19 A. Not at all.
 20 Q. And you're not saying they're
 21 doing unreasonable science?
 22 A. Not at all.
 23 Q. And you're not saying that the
 24 methods that they've used to reach those
 25 conclusions are scientifically invalid ones,

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1 right?
 2 A. No, I think -- as I said, I
 3 think everyone is doing their best job with
 4 all the data they have available, and all of
 5 these articles have gone through peer review,
 6 which means there are other scientists that
 7 agree, this is important information to put
 8 out there. But that's not the same thing as
 9 establishing a causal association.
 10 Q. But including the papers that
 11 say, we think this strengthens the causal
 12 inference and so on, those went through peer
 13 review, right?
 14 MR. MURDICA: Objection to
 15 form.
 16 THE WITNESS: They did.
 17 QUESTIONS BY MR. SNIDOW:
 18 Q. And so you don't think that's
 19 an unreasonable thing to say, right?
 20 A. I think --
 21 MR. MURDICA: Objection to
 22 form.
 23 Go ahead.
 24 THE WITNESS: I think everybody
 25 is, again, trying to provide evidence

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1 that addresses the question of whether
 2 there is a true causal association,
 3 and I -- that's all I can say, is that
 4 people are doing the best with the
 5 data they have.
 6 QUESTIONS BY MR. SNIDOW:
 7 Q. And analyzing that data using
 8 scientifically reasonable means, right?
 9 MR. MURDICA: Objection to
 10 form.
 11 THE WITNESS: I think that
 12 these are scientifically reasonable
 13 means to address the question using
 14 the data that they have available.
 15 The data isn't perfect.
 16 QUESTIONS BY MR. SNIDOW:
 17 Q. Including the authors that you
 18 disagree with, right?
 19 MR. MURDICA: Objection to
 20 form.
 21 THE WITNESS: I'm not
 22 understanding that question.
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Yeah. The authors -- including
 25 the authors you disagree with on the

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1 causation question, confounding and so on,
 2 they're using scientifically reasonable means
 3 to address the data using imperfect data?
 4 MR. MURDICA: Objection to
 5 form.
 6 THE WITNESS: So they're using
 7 scientific means to address the
 8 question using imperfect data, and
 9 almost universally they're
 10 acknowledging the potential problems
 11 with drawing any causal conclusion
 12 from their data. Saying that
 13 something adds evidence or support is
 14 not the same as saying it causes.
 15 QUESTIONS BY MR. SNIDOW:
 16 Q. Do you see in Baker that they
 17 adjusted for hospital-administered
 18 acetaminophen?
 19 A. I did see that.
 20 Q. All right. And we were talking
 21 earlier about how when you're looking for a
 22 confounder and you adjust for it and the
 23 results don't change, that's evidence against
 24 the confounding?
 25 MR. MURDICA: Objection to

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1 form.

2 THE WITNESS: Well, it suggests

3 that the results are not confounded by

4 that specific factor. It's not

5 evidence against all confounding.

6 QUESTIONS BY MR. SNIDOW:

7 Q. And the specific factor was

8 hospital-administered meconium?

9 Hospital-administered --

10 A. I hope not.

11 Q. Yeah.

12 Hospital-administered APAP?

13 A. Sorry. Correct.

14 Q. Correct.

15 And that was the example you're

16 giving about -- did you say your sis --

17 A. To my daughter.

18 Q. Your daughter. Okay.

19 That was the example you were

20 giving, right?

21 A. Well, it was one example. She

22 also took oral Tylenol or oral acetaminophen,

23 whatever we -- I don't know exactly what the

24 brand was, but she took it in the hospital in

25 front of me and then proceeded to nurse her

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1 babies for several days before he had his

2 first poop.

3 Q. And they adjusted for that in

4 Baker?

5 MR. MURDICA: Objection to

6 form.

7 THE WITNESS: Well, that's not

8 injection. That's oral.

9 QUESTIONS BY MR. SNIDOW:

10 Q. No, but they adjusted for

11 hospital-administered acetaminophen?

12 MR. MURDICA: Objection to

13 form.

14 QUESTIONS BY MR. SNIDOW:

15 Q. And the results didn't change?

16 A. I need to look. I don't

17 recall.

18 Q. Okay.

19 A. But irrespective of that, it

20 doesn't change my evaluation of the

21 contribution of this to the overall question

22 of causation because of the issue of timing,

23 dose and duration, which is just absent. We

24 don't know throughout pregnancy how the --

25 women's use of acetaminophen correlates with

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1 the measure of meconium.

2 Q. Are you looking for that still?

3 MR. MURDICA: Objection to

4 form.

5 THE WITNESS: I'm just seeing

6 if I can find it, yeah.

7 I think it's probably in the

8 supplements because I don't see it.

9 QUESTIONS BY MR. SNIDOW:

10 Q. All right. Don't worry about

11 it.

12 Let me ask you this, though.

13 If that's true, if they did adjust for

14 hospital-administered acetaminophen, that

15 would suggest that they're reporting results

16 for acetaminophen that was taken during

17 pregnancy, right?

18 MR. MURDICA: Objection to

19 form.

20 THE WITNESS: I would like to

21 see the exact numbers and how they

22 adjusted for it. So it's hard for me

23 to -- without seeing the numbers, it's

24 hard for me to determine.

25

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1 QUESTIONS BY MR. SNIDOW:

2 Q. Okay. While we're looking for

3 that, so you can see it, would you agree that

4 results in Baker --

5 MR. MURDICA: He's asking you a

6 question.

7 THE WITNESS: I'm sorry. I'm

8 just trying to see if I could look in

9 the supplementary materials in order

10 to answer that question.

11 QUESTIONS BY MR. SNIDOW:

12 Q. It's all right. We'll dig it

13 up. It will be faster.

14 Do you agree these --

15 A. I mean, I have it right in my

16 binder. I can just look at it.

17 Q. Let me just find where it is in

18 the table. I'm not -- I'll let you read it,

19 I promise.

20 Do you see where it says "No

21 acetaminophen" and "Yes acetaminophen"?

22 A. I see that, yes.

23 Q. And this is the first result in

24 Baker. They did a yes/no comparison?

25 A. No acetaminophen and

<p style="text-align: right;">Page 510</p> <p>1 acetaminophen, yes.</p> <p>2 Q. Did I accurately capture the</p> <p>3 results of Table 2?</p> <p>4 A. You did, the adjusted analysis,</p> <p>5 the weighted -- the weighted analysis, I will</p> <p>6 say. That's what they call it.</p> <p>7 Q. So in this study, the kids who</p> <p>8 had acetaminophen in their meconium had twice</p> <p>9 the likelihood of developing ADHD however</p> <p>10 many years later, right?</p> <p>11 MR. MURDICA: Objection to the</p> <p>12 form.</p> <p>13 THE WITNESS: The results</p> <p>14 support an increased risk of ADHD</p> <p>15 among children in whom meconium -- in</p> <p>16 whom APAP was detected in their</p> <p>17 meconium.</p> <p>18 I'm really getting tired.</p> <p>19 QUESTIONS BY MR. SNIDOW:</p> <p>20 Q. Yeah.</p> <p>21 And not just an increased risk,</p> <p>22 a doubling of the risk, right?</p> <p>23 A. That's what they report in</p> <p>24 their study.</p> <p>25 Q. And similarly here, they did a</p>	<p style="text-align: right;">Page 512</p> <p>1 confidence interval is 2.4?</p> <p>2 A. Uh-huh.</p> <p>3 Q. The point estimate suggests a</p> <p>4 310 percent increase in the risk of ADHD?</p> <p>5 A. That's correct.</p> <p>6 Q. The high end of the confidence</p> <p>7 interval suggests a 609 -- sorry, a 595</p> <p>8 percent increase in the risk of ADHD?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: That's how we can</p> <p>12 interpret a confidence interval, yes.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. All right. And I imagine if I</p> <p>15 show you these again, you think that's</p> <p>16 stronger or weaker than the secondhand smoke</p> <p>17 result?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: Again, I'm not</p> <p>21 going to compare across a completely</p> <p>22 different question and completely</p> <p>23 different exposure and a completely</p> <p>24 different outcome. It's not a fair</p> <p>25 comparison.</p>
<p style="text-align: right;">Page 511</p> <p>1 dose-response analysis, right?</p> <p>2 MR. MURDICA: Objection to</p> <p>3 form. Use of the demonstrative.</p> <p>4 Answer it, if you can.</p> <p>5 THE WITNESS: So they used the</p> <p>6 levels in the meconium and</p> <p>7 characterized that as no, low or high.</p> <p>8 It's unclear to me exactly what that</p> <p>9 means. And then they looked to see</p> <p>10 whether the risk varied across those</p> <p>11 levels.</p> <p>12 And in the low APAP, it</p> <p>13 appeared that there was not a</p> <p>14 significant risk. In the high APAP,</p> <p>15 it appeared that there was, with quite</p> <p>16 a substantially wide confidence</p> <p>17 interval.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. The risk ratio for high APAP</p> <p>20 use was 4.1?</p> <p>21 A. That's what they report.</p> <p>22 Q. That is a statistically</p> <p>23 significant result?</p> <p>24 A. It is.</p> <p>25 Q. The minimum they report in the</p>	<p style="text-align: right;">Page 513</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Well, this had a risk ratio of</p> <p>3 1.3, I think we saw?</p> <p>4 A. Again, we need to consider what</p> <p>5 the exposure is, how the exposure was</p> <p>6 measured, how reliable that is, what the</p> <p>7 outcome is. All of those things go into my</p> <p>8 evaluation. So just looking at the numbers</p> <p>9 is not a sufficient way to compare those two,</p> <p>10 in my mind.</p> <p>11 Q. This risk ratio is 4?</p> <p>12 A. We've said that this -- we've</p> <p>13 already established that, yes.</p> <p>14 Q. And that's, what, hundreds of</p> <p>15 percent higher than the secondhand smoke one?</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. Is that right?</p> <p>20 A. Again, I'm not going to compare</p> <p>21 the results from a secondhand smoke study</p> <p>22 with very different exposure classification,</p> <p>23 measurement, precision, et cetera, to a study</p> <p>24 of meconium. It just doesn't -- it's not the</p> <p>25 way I would -- the way I do things.</p>

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1 MR. SNIDOW: Jim, do you want
2 to take a break and see what I can do
3 to wrap up?
4 MR. MURDICA: Okay.
5 MR. SNIDOW: Thanks.
6 VIDEOGRAPHER: The time is
7 4:57 p.m., and we're off the record.
8 (Off the record at 4:57 p.m.)
9 VIDEOGRAPHER: The time is
10 5:11 p.m., and we're on the record.
11 QUESTIONS BY MR. SNIDOW:
12 Q. All right. Dr. Pinto-Martin,
13 when assessing whether results in studies
14 that report multiple results are
15 statistically significant, are you familiar
16 with a concept of a Bonferroni correction?
17 A. I am. I refer to it in my
18 report.
19 Q. Yeah.
20 And what you do there is when
21 you're reporting lots of results, that
22 increases the likelihood of a chance finding,
23 right?
24 A. That's correct.
25 Q. And I think the classic example

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1 is -- are you familiar with the study where
2 they regress the zodiac signs on cardiac
3 outcomes? No?
4 A. No, I'm not.
5 Q. Okay. You'll like this one.
6 You should teach this one, too.
7 They found that two of the
8 signs had statistically significant results
9 as a matter of chance, and so you use it to
10 illustrate why you got a Bonferroni
11 correction.
12 Did you do a Bonferroni
13 correction on any of the studies in the
14 literature?
15 A. I did not. That was not part
16 of what I was assigned to do. I was assigned
17 to review the studies as they were published.
18 And so I certainly noted when I
19 thought they should have done one and didn't,
20 but I didn't conduct my own.
21 Q. Could you have done that?
22 A. Perhaps, if I'd had access to
23 the data. It's hard to know whether you
24 actually have access to the raw data in order
25 to conduct something like that.

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1 Q. But that would have given you
2 more information that -- as to whether or not
3 there was a multiplicity issue, right?
4 A. Certainly. Doing the
5 Bonferroni will tell you whether there's an
6 issue there or not, but, again, without the
7 raw data, that's just a hypothetical.
8 Q. Right.
9 But you didn't -- you didn't do
10 one, did you?
11 A. I had no desire to do one,
12 frankly. As I said, I reviewed the reported
13 results from the authors and commented on
14 those.
15 Q. Okay. Will you look at Baker
16 again for me? It's the last one we were
17 doing.
18 A. Yeah.
19 Q. Do you see here on page 1075 --
20 hold on a second.
21 A. Where are we? Yeah. 1075,
22 yeah.
23 Q. You see above, "To explore
24 potential dose-response association." It
25 says, "In a sensitivity analysis, we excluded

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1 all mothers who were administered
2 acetaminophen during delivery," right?
3 A. Uh-huh.
4 Q. It says, "To account for
5 potential confounding by indication for use
6 during labor"?
7 A. Uh-huh.
8 Q. All right. So they did a
9 sensitivity analysis there, right?
10 A. Right. So a sensitivity
11 analysis is a -- an attempt to control for
12 something but not necessarily based on data.
13 And again, this is during
14 labor. So I think we were talking about the
15 hospital administration. That was your --
16 the term you used, and so I'm talking about
17 oral administration post C-section. That's
18 not during labor; it's post-labor.
19 So, you know, a woman can be
20 given acetaminophen, and of course she will
21 ask for it after a C-section because she's in
22 pain, and then continue to take it during her
23 stay in the hospital and before her baby's
24 meconium is collected.
25 Q. But the baby at that point is

<p style="text-align: right;">Page 518</p> <p>1 out of the body?</p> <p>2 A. The baby at that point is out</p> <p>3 of the body.</p> <p>4 Q. And it's going into the baby</p> <p>5 via, in your theory, breast milk?</p> <p>6 A. It's not a theory. It's -- we</p> <p>7 know that --</p> <p>8 Q. Do they say that in Baker? I'm</p> <p>9 sorry, I didn't mean to interrupt you.</p> <p>10 Do they say that in Baker?</p> <p>11 MR. MURDICA: Hang on a second.</p> <p>12 You just -- you said you were sorry to</p> <p>13 interrupt her, and then you actually</p> <p>14 interrupted her.</p> <p>15 You have let her answer the</p> <p>16 question before you ask a new one.</p> <p>17 QUESTIONS BY MR. SNIDOW:</p> <p>18 Q. Go ahead.</p> <p>19 A. That's not something Baker</p> <p>20 addresses at all, which is why I think it's</p> <p>21 important to consider. He does not address</p> <p>22 the potential exposure through breastfeeding</p> <p>23 that would then result in an elevated level</p> <p>24 of acetaminophen in the meconium of the baby.</p> <p>25</p>	<p style="text-align: right;">Page 520</p> <p>1 did not. My daughter hadn't had her</p> <p>2 baby yet, and I was struck by the fact</p> <p>3 that I was witnessing exactly what he</p> <p>4 was talking about because she was</p> <p>5 taking acetaminophen after pregnancy,</p> <p>6 she was nursing her baby.</p> <p>7 And the meconium -- I wished I</p> <p>8 could have collected his meconium, in</p> <p>9 fact.</p> <p>10 QUESTIONS BY MR. SNIDOW:</p> <p>11 Q. Well, right.</p> <p>12 But you weren't witnessing the</p> <p>13 acetaminophen go through the breast milk into</p> <p>14 the baby's meconium, right?</p> <p>15 A. No, and --</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. And you didn't talk about that</p> <p>20 at all in your report?</p> <p>21 MR. MURDICA: Objection to</p> <p>22 form.</p> <p>23 Which question do you want her</p> <p>24 to -- come on.</p> <p>25</p>
<p style="text-align: right;">Page 519</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Do you have a paper or really</p> <p>3 any authority suggesting that a mother taking</p> <p>4 acetaminophen who is breastfeeding can end up</p> <p>5 in the meconium of the baby who's out of the</p> <p>6 body?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. Do you have a paper for that?</p> <p>11 A. I don't have a paper for that.</p> <p>12 Q. Okay.</p> <p>13 A. I just know that that is a</p> <p>14 fact.</p> <p>15 Q. Oh, you know it's a fact?</p> <p>16 A. I know that I've heard it.</p> <p>17 I've read it. I don't know exactly where the</p> <p>18 information comes from, but meconium</p> <p>19 continues to accumulate exposures until it's</p> <p>20 released from the baby's body.</p> <p>21 Q. And in your write-up of Baker</p> <p>22 in your report, did you say any of that?</p> <p>23 MR. MURDICA: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: Interestingly, I</p>	<p style="text-align: right;">Page 521</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. In your report --</p> <p>3 MR. MURDICA: Ask a question.</p> <p>4 QUESTIONS BY MR. SNIDOW:</p> <p>5 Q. In your report, did you ever</p> <p>6 flag the possibility that a mother might</p> <p>7 introduce acetaminophen into the baby's</p> <p>8 meconium while breastfeeding and then that</p> <p>9 could have somehow messed up the Baker</p> <p>10 results?</p> <p>11 MR. MURDICA: Asked and</p> <p>12 answered.</p> <p>13 QUESTIONS BY MR. SNIDOW:</p> <p>14 Q. Did you say that?</p> <p>15 A. Again --</p> <p>16 MR. MURDICA: Objection.</p> <p>17 THE WITNESS: -- I said it was</p> <p>18 not a concept that I had thought about</p> <p>19 while -- when I was writing my report.</p> <p>20 It was something that occurred to me</p> <p>21 afterwards, so...</p> <p>22 QUESTIONS BY MR. SNIDOW:</p> <p>23 Q. When did your daughter have her</p> <p>24 baby?</p> <p>25 A. The end of July.</p>

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1 Q. All right. So in the past
2 month, you could have updated your report,
3 right?
4 MR. MURDICA: Objection to
5 form.
6 THE WITNESS: I could have
7 updated my report. I did not update
8 my report. It's an anecdotal piece of
9 evidence that I thought was worth
10 pointing out.
11 QUESTIONS BY MR. SNIDOW:
12 Q. Yeah. It's -- it is anecdotal,
13 true? Right?
14 MR. MURDICA: Objection to
15 form.
16 QUESTIONS BY MR. SNIDOW:
17 Q. And do you typically rely on
18 anecdotal evidence in your field?
19 MR. MURDICA: Objection to
20 form.
21 THE WITNESS: I do not. I rely
22 on published epidemiologic literature.
23 QUESTIONS BY MR. SNIDOW:
24 Q. Have you heard --
25 A. I just thought it was an

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1 interesting story.
2 Q. Well, I did, too, but now --
3 you're using it to undermine the published
4 peer-reviewed study, so I've got to explore
5 that.
6 A. I'm suggesting that it might
7 have an impact. I think there are other
8 reasons to -- and I've already stated them,
9 to question the results of this study with
10 respect to contributing to the evidence on
11 causal association between acetaminophen and
12 ADHD or ASD.
13 Q. Okay. Are you familiar with
14 the max in your field, the plural of anecdote
15 is not data?
16 MR. MURDICA: Objection to
17 form.
18 THE WITNESS: I am.
19 QUESTIONS BY MR. SNIDOW:
20 Q. Do you agree with that one, by
21 the way? I mean, isn't the plural of
22 anecdote data?
23 MR. MURDICA: Objection to
24 form.
25 THE WITNESS: I do not agree

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1 with that.
2 QUESTIONS BY MR. SNIDOW:
3 Q. Okay. All right. If the FDA
4 said that the literature linking
5 acetaminophen exposure to ADHD was
6 consistent, would you disagree?
7 MR. MURDICA: Objection to
8 form.
9 THE WITNESS: I'm sorry, I
10 don't know what's happening.
11 MS. BARRIERE: I think we asked
12 her a question.
13 QUESTIONS BY MR. SNIDOW:
14 Q. Oh, you said, I'm sorry, I
15 don't know. I did not -- I did not hear you.
16 MR. MURDICA: No. I think this
17 is all confused because you're looking
18 over there and --
19 THE WITNESS: I don't know
20 what's happening. Yeah.
21 MR. MURDICA: Why don't -- why
22 don't you ask a new question.
23 QUESTIONS BY MR. SNIDOW:
24 Q. If the FDA said that literature
25 linking acetaminophen exposure to ADHD was

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1 consistent, would you disagree?
2 A. So I would want to know where
3 that statement was made and in what context
4 and for what purpose. And again, I've
5 described my definition of consistency, which
6 I think incorporates things that others may
7 not, including the FDA.
8 I don't -- I don't know, you
9 know, the purpose of that -- of that
10 statement by the FDA.
11 Q. Do you think you might agree?
12 MR. MURDICA: Objection to
13 form.
14 THE WITNESS: I don't believe
15 that this literature establishes a
16 consistent association, so...
17 QUESTIONS BY MR. SNIDOW:
18 Q. Okay.
19 A. That's my finding.
20 (Pinto-Martin Exhibit 631
21 marked for identification.)
22 QUESTIONS BY MR. SNIDOW:
23 Q. All right. I'm going to mark
24 631, which is the Bradford Hill address.
25 Can you see if there's

<p style="text-align: right;">Page 526</p> <p>1 highlighting on that, Doctor?</p> <p>2 A. It doesn't appear to have</p> <p>3 highlighting.</p> <p>4 Q. Great.</p> <p>5 Okay. Would you agree that the</p> <p>6 method laid out in the Bradford Hill address</p> <p>7 is considered the classic way to do causation</p> <p>8 analysis in your field?</p> <p>9 MR. MURDICA: Objection. Form.</p> <p>10 THE WITNESS: I think that the</p> <p>11 majority of epidemiologists use the</p> <p>12 Bradford Hill as a method of assessing</p> <p>13 a body of literature with respect to a</p> <p>14 causal association.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. You agree that's the right way</p> <p>17 to assess causation?</p> <p>18 MR. MURDICA: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I don't know if I</p> <p>21 think it's right or wrong. It is what</p> <p>22 we use. It's -- it -- it's the</p> <p>23 established method. I don't know what</p> <p>24 you mean by "right," but it's the</p> <p>25 established method.</p>	<p style="text-align: right;">Page 528</p> <p>1 was gathered and some of the other stuff that</p> <p>2 you've mentioned today when deciding whether</p> <p>3 association is strong?</p> <p>4 MR. MURDICA: Objection to</p> <p>5 form.</p> <p>6 You can answer.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Does it say to do that?</p> <p>9 MR. MURDICA: Objection to</p> <p>10 form.</p> <p>11 You answer it, you if you can.</p> <p>12 THE WITNESS: The Bradford Hill</p> <p>13 criteria are a set of very simple</p> <p>14 statements about those criterion, and</p> <p>15 he does not tell us, you know, how to</p> <p>16 apply those to real world data that we</p> <p>17 are evaluating, much less a body of</p> <p>18 evidence that we are evaluating.</p> <p>19 So that's my own expertise</p> <p>20 coming into play after years of</p> <p>21 reading studies, evaluating studies,</p> <p>22 understanding whether a purported</p> <p>23 association is strong just by virtue</p> <p>24 of its size or strong because it is</p> <p>25 meaningful in terms of the association</p>
<p style="text-align: right;">Page 527</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. I don't know what the</p> <p>3 difference between that is either, but if you</p> <p>4 think it's the established, that's fine.</p> <p>5 If you look here under</p> <p>6 Strength?</p> <p>7 A. Uh-huh.</p> <p>8 Q. Now, today you -- you've told</p> <p>9 me a few times that for strength, you need to</p> <p>10 look at the underlying data before you can</p> <p>11 determine whether a -- an association is</p> <p>12 strong or not, right?</p> <p>13 A. So what I've tried to explain</p> <p>14 is that a strong association can still be</p> <p>15 flawed, and so you could have an odds ratio</p> <p>16 of 5, for example, or a relative risk of 5,</p> <p>17 that was either completely biased or</p> <p>18 confounded and, therefore, not representative</p> <p>19 of a strong association.</p> <p>20 So taking the point estimate in</p> <p>21 isolation, in my mind, is an incomplete</p> <p>22 evaluation of strength.</p> <p>23 Q. Okay. But can you tell me</p> <p>24 where in the Bradford Hill address it says</p> <p>25 you need to look at, like, how the exposure</p>	<p style="text-align: right;">Page 529</p> <p>1 that it represents.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. So that's a no. Bradford Hill</p> <p>4 doesn't say to go look at the underlying</p> <p>5 data?</p> <p>6 MR. MURDICA: Objection to</p> <p>7 form.</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. You can -- you can look.</p> <p>10 A. Bradford Hill does not address</p> <p>11 how to apply the criteria. He describes the</p> <p>12 criteria and does not give us specific</p> <p>13 instructions about how to prioritize them or</p> <p>14 use them in an evaluation.</p> <p>15 And I think that is the way</p> <p>16 that he wanted to put them out there, and</p> <p>17 then the utility of them has evolved over</p> <p>18 time.</p> <p>19 Q. All right. So for consistency,</p> <p>20 he says, "Has it been repeatedly observed by</p> <p>21 different persons, in different places,</p> <p>22 circumstances and times"?</p> <p>23 A. That's correct.</p> <p>24 Q. And you'd agree that the</p> <p>25 association between APAP and ADHD and ASD has</p>

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1 been observed by different persons, in
 2 different places, circumstances and times,
 3 right?
 4 MR. MURDICA: Objection to
 5 form.
 6 THE WITNESS: So observed is
 7 the relevant point here. I think
 8 there are studies that demonstrate
 9 that they have support for a causal
 10 association and studies that don't.
 11 The consistency in terms of
 12 timing is all over the place, and the
 13 term -- the consistency in terms of
 14 dose is not there.
 15 And so consistency, again, is
 16 considered in the context of the
 17 overall body of evidence, and in my
 18 mind, the consistency criteria is not
 19 met.
 20 QUESTIONS BY MR. SNIDOW:
 21 Q. Where does Bradford Hill say to
 22 consider really any of that? Dose? What
 23 else did you say? Time?
 24 Does he say to do any of that?
 25 MR. MURDICA: Objection to the

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1 form of the question.
 2 THE WITNESS: As I said, he was
 3 laying out a set of criteria to be
 4 applied in the real world to a body of
 5 evidence, and I believe that the
 6 approach that I use is the correct
 7 approach for evaluating consistency
 8 and the other criteria.
 9 QUESTIONS BY MR. SNIDOW:
 10 Q. Well, I know you think it's
 11 right, but is that what Bradford Hill says?
 12 Can you find it here?
 13 MR. MURDICA: Objection.
 14 You've now done this five times. I
 15 think that's enough, J.J.
 16 MR. SNIDOW: Okay.
 17 THE WITNESS: As I said, that
 18 was not what he did in this report.
 19 He was laying out the criteria for us
 20 to use in our evaluation in the real
 21 world.
 22 QUESTIONS BY MR. SNIDOW:
 23 Q. All right. Specificity is
 24 next. Agree that one is just very rarely
 25 satisfied, true?

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1 A. Depends on the body of
 2 evidence. Sometimes it's very nicely
 3 satisfied. It's certainly not satisfied in
 4 the APAP and neurodevelopmental outcome.
 5 Q. It's certainly not satisfied in
 6 tobacco and lung cancer, right?
 7 MR. MURDICA: Objection to
 8 form.
 9 THE WITNESS: Again, there's
 10 examples where it's satisfied and
 11 examples where it's not.
 12 I'm saying in this literature,
 13 it is clearly not satisfied.
 14 QUESTIONS BY MR. SNIDOW:
 15 Q. Right.
 16 And Bradford Hill says that's
 17 okay, right?
 18 He says, "If specificity
 19 exists, we may be able to draw conclusions
 20 without hesitation. If it's not apparent,
 21 we're not thereby necessarily left sitting
 22 irresolutely on the fence."
 23 Right?
 24 A. That's what it says.
 25 Q. All right. Temporality, he

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1 says, that's about which is the cart and
 2 which is the horse, right?
 3 A. Uh-huh.
 4 Q. That's a statement about
 5 reverse causation?
 6 MR. MURDICA: Objection to
 7 form.
 8 THE WITNESS: That's --
 9 QUESTIONS BY MR. SNIDOW:
 10 Q. Yes?
 11 A. -- part of what he's
 12 considering there, yes --
 13 Q. Well --
 14 A. -- in the criterion.
 15 Q. That is what he's saying here,
 16 which is the cart, which is the horse; that's
 17 about reverse causation?
 18 MR. MURDICA: Objection to
 19 form.
 20 THE WITNESS: Well, it's about
 21 whether the exposure precedes the
 22 outcome, yeah.
 23 QUESTIONS BY MR. SNIDOW:
 24 Q. Does a particular diet lead to
 25 disease, or do the early stages of the

<p style="text-align: right;">Page 534</p> <p>1 disease lead to those particular diet</p> <p>2 particular habits. That's about reverse</p> <p>3 causation?</p> <p>4 A. So it's about both, right.</p> <p>5 It's about, is there a causal pathway towards</p> <p>6 disease, or is the effect of the disease on</p> <p>7 the exposure what we're measuring here.</p> <p>8 So he's saying both. He's</p> <p>9 saying it could be we see exposure to</p> <p>10 outcome, or it could be that the outcome is</p> <p>11 affecting the exposure. I think he's</p> <p>12 describing both.</p> <p>13 Q. And in this literature here,</p> <p>14 you know, the way it kind of worked, was for</p> <p>15 the cohort study, take Liew 2016 as an</p> <p>16 example, they followed women, you know, kind</p> <p>17 of a time -- they followed them at time A,</p> <p>18 asked them about APAP use, waited ten years</p> <p>19 or so, and then looked at ADHD diagnoses?</p> <p>20 A. So I'd like to know what</p> <p>21 specific study you're referring to. I'm</p> <p>22 pretty tired right now and just to throw</p> <p>23 something out like that, I'm not quite sure</p> <p>24 exactly what you're referring to.</p> <p>25 But I can tell you about the</p>	<p style="text-align: right;">Page 536</p> <p>1 heritable, and we know that women who</p> <p>2 have one child with autism are more</p> <p>3 likely to have another child with</p> <p>4 autism. So her result in one</p> <p>5 pregnancy could affect her</p> <p>6 acetaminophen use and lots of other</p> <p>7 things in subsequent pregnancies.</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. The strongest you'll give me on</p> <p>10 that is that it's highly unlikely that</p> <p>11 there's reverse causation?</p> <p>12 MR. MURDICA: Objection to</p> <p>13 the -- to the form in which you're</p> <p>14 asking the question.</p> <p>15 THE WITNESS: I'm not really</p> <p>16 understanding your question, quite</p> <p>17 frankly.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. All right. Here's how the</p> <p>20 studies work, right? The mother takes APAP,</p> <p>21 they wait a long time, they see whether the</p> <p>22 kid gets ADHD, right?</p> <p>23 MR. MURDICA: Object to the</p> <p>24 form.</p> <p>25</p>
<p style="text-align: right;">Page 535</p> <p>1 methods of the study, if that's what you're</p> <p>2 asking about.</p> <p>3 Q. Let me ask it a different way.</p> <p>4 Do you think reverse causation</p> <p>5 is a possibility in this literature?</p> <p>6 MR. MURDICA: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: Can you describe</p> <p>9 what that reverse causation hypothesis</p> <p>10 would be?</p> <p>11 QUESTIONS BY MR. SNIDOW:</p> <p>12 Q. Sure.</p> <p>13 Do you think that the child's</p> <p>14 diagnosis of ADHD could have caused the</p> <p>15 mother to take acetaminophen ten years</p> <p>16 earlier?</p> <p>17 MR. MURDICA: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I think that</p> <p>20 that, as you presented it, is a highly</p> <p>21 unlikely scenario, but I do believe</p> <p>22 that maternal genetics can have an</p> <p>23 impact on the risk of a future child</p> <p>24 having autism.</p> <p>25 So we know that autism is</p>	<p style="text-align: right;">Page 537</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. Is that basically right?</p> <p>3 A. In some of those cohort</p> <p>4 studies, that's -- yeah.</p> <p>5 Q. I'm asking you, is there any</p> <p>6 possibility that this caused that ten years</p> <p>7 earlier?</p> <p>8 MR. MURDICA: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: And I think I</p> <p>11 answered it. I don't think that</p> <p>12 that's likely. I think that the</p> <p>13 maternal genetic predisposition to</p> <p>14 having a child without -- with autism</p> <p>15 could affect a subsequent pregnancy.</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. When you say it's not likely, I</p> <p>18 mean, is it possible? Does she have a time</p> <p>19 machine?</p> <p>20 MR. MURDICA: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: I think I've</p> <p>23 answered the question.</p> <p>24 QUESTIONS BY MR. SNIDOW:</p> <p>25 Q. Okay. But you're leaving open</p>

<p style="text-align: right;">Page 538</p> <p>1 the possibility that this causes that, right?</p> <p>2 A. No, I said --</p> <p>3 MR. MURDICA: Object --</p> <p>4 THE WITNESS: I mean, if you</p> <p>5 want me to say it in a more strong</p> <p>6 term, I will.</p> <p>7 QUESTIONS BY MR. SNIDOW:</p> <p>8 Q. Yes, please.</p> <p>9 A. I don't think it's possible.</p> <p>10 Q. All right. There you go.</p> <p>11 All right.</p> <p>12 A. Can I just point out that</p> <p>13 that's not the only thing that Bradford Hill</p> <p>14 was pointing out in that -- in that</p> <p>15 criterion?</p> <p>16 Q. Okay. Biological gradient.</p> <p>17 That's dose-response?</p> <p>18 A. That's correct.</p> <p>19 Q. Okay. And what he says was,</p> <p>20 "For instance, the fact that the death rate</p> <p>21 from cancer of the lung rises linearly with</p> <p>22 the number of cigarettes smoked daily, adds a</p> <p>23 very great deal to the simpler evidence that</p> <p>24 cigarette smokers have a higher death rate</p> <p>25 than nonsmokers."</p>	<p style="text-align: right;">Page 540</p> <p>1 QUESTIONS BY MR. SNIDOW:</p> <p>2 Q. My point is this is</p> <p>3 self-reported data.</p> <p>4 A. Perhaps. Perhaps. Perhaps it</p> <p>5 was counting cigarette butts. Perhaps it was</p> <p>6 partner exposure. I have no idea.</p> <p>7 Q. You think -- you think that in</p> <p>8 the '50s and '60s that they had studies where</p> <p>9 they were counting cigarette butts to measure</p> <p>10 tobacco exposure?</p> <p>11 MR. MURDICA: Object- --</p> <p>12 objection to the form of the question.</p> <p>13 THE WITNESS: I think it's</p> <p>14 possible.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. Now, where in Bradford Hill's</p> <p>17 analysis does he say to consider any of that?</p> <p>18 That you need really tight exposure data</p> <p>19 before you can do a dose-response analysis?</p> <p>20 MR. MURDICA: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: I think an</p> <p>23 epidemiologist with integrity would</p> <p>24 think very carefully about the basis</p> <p>25 for any purported association, and</p>
<p style="text-align: right;">Page 539</p> <p>1 Right?</p> <p>2 A. That's correct.</p> <p>3 Q. And you think that you need</p> <p>4 really good exposure data in order to be able</p> <p>5 to do that kind of analysis?</p> <p>6 A. I certainly believe we need</p> <p>7 exposure data that is better than what we</p> <p>8 have in the APAP literature.</p> <p>9 Q. And you think in 19 -- you</p> <p>10 think in 1965, they had, what, prescription</p> <p>11 databases for tobacco use?</p> <p>12 A. I don't --</p> <p>13 MR. MURDICA: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: I don't believe</p> <p>16 they had prescription databases for</p> <p>17 tobacco use. It's, I would say, an</p> <p>18 easier proposition to describe the</p> <p>19 number of cigarettes you smoked per</p> <p>20 day, most people can -- back in the</p> <p>21 day would smoke a pack or more. So</p> <p>22 they often characterized it by packs</p> <p>23 and not just single cigarettes. So I</p> <p>24 just --</p> <p>25</p>	<p style="text-align: right;">Page 541</p> <p>1 part of that would be looking at the</p> <p>2 integrity of the exposure information.</p> <p>3 So he doesn't say it, as you --</p> <p>4 as you've repeatedly pointed out, he</p> <p>5 doesn't contextualize, but I do. And</p> <p>6 I think contextualizing is absolutely</p> <p>7 essential when you're evaluating a</p> <p>8 body of literature.</p> <p>9 QUESTIONS BY MR. SNIDOW:</p> <p>10 Q. All right. Biological</p> <p>11 plausibility, right? You're not an expert in</p> <p>12 biological plausibility, are you?</p> <p>13 MR. MURDICA: Objection to</p> <p>14 form.</p> <p>15 We're really retreading ground</p> <p>16 here.</p> <p>17 THE WITNESS: I am not.</p> <p>18 QUESTIONS BY MR. SNIDOW:</p> <p>19 Q. Okay. And then in your report</p> <p>20 you say that it's not -- that this</p> <p>21 association is not biologically plausible</p> <p>22 because they don't know for sure what the</p> <p>23 mechanism is, right?</p> <p>24 A. The mechanism that they</p> <p>25 proposed -- the mechanisms that are proposed</p>

<p style="text-align: right;">Page 542</p> <p>1 are all hypotheses, and we have no human data</p> <p>2 to support those hypotheses.</p> <p>3 So, yes, we don't have that</p> <p>4 biological plausibility.</p> <p>5 Q. Is there ever going to be human</p> <p>6 data on biological plausibility?</p> <p>7 MR. MURDICA: Object to the</p> <p>8 form of the question.</p> <p>9 THE WITNESS: I can't answer</p> <p>10 that question. I don't know. I don't</p> <p>11 know what the future will bring.</p> <p>12 QUESTIONS BY MR. SNIDOW:</p> <p>13 Q. Well, this is about how to go</p> <p>14 from observational studies to causation,</p> <p>15 right?</p> <p>16 MR. MURDICA: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: These are a set</p> <p>19 of criteria that we use to evaluate a</p> <p>20 body of evidence, which is what I did.</p> <p>21 QUESTIONS BY MR. SNIDOW:</p> <p>22 Q. And what does the word</p> <p>23 "plausible" mean?</p> <p>24 A. Possible. I don't know what a</p> <p>25 synonym would be. Possible.</p>	<p style="text-align: right;">Page 544</p> <p>1 A. Right. And I think that that's</p> <p>2 an ecological assessment of using data that</p> <p>3 was much easier to acquire than what we are</p> <p>4 looking at here. Because of the changes in</p> <p>5 diagnostic criteria and awareness, as we</p> <p>6 know, that have had a profound impact on the</p> <p>7 prevalence of autism, it's very difficult for</p> <p>8 us to make the same kind of ecological</p> <p>9 argument.</p> <p>10 Q. Well, but the skeptics said the</p> <p>11 same thing about tobacco, right? They said</p> <p>12 it was because of the development of X-rays</p> <p>13 and so on?</p> <p>14 A. I don't know. I wasn't reading</p> <p>15 that literature back in the day.</p> <p>16 Q. We looked at it just, like, two</p> <p>17 hours ago, right?</p> <p>18 MR. MURDICA: Object to the</p> <p>19 form.</p> <p>20 QUESTIONS BY MR. SNIDOW:</p> <p>21 Q. Do you not remember?</p> <p>22 MR. MURDICA: Objection.</p> <p>23 THE WITNESS: Again, it's not</p> <p>24 something that I used to look at the</p> <p>25 evidence at APAP and</p>
<p style="text-align: right;">Page 543</p> <p>1 Q. Possible.</p> <p>2 A. Likely, maybe. Possibly</p> <p>3 likely. It's a little more than possible.</p> <p>4 Q. You've read the literature that</p> <p>5 identified several potential causal pathways,</p> <p>6 right?</p> <p>7 MR. MURDICA: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: I have read the</p> <p>10 literature that hypothesizes causal</p> <p>11 mechanisms.</p> <p>12 Again, I will repeat that there</p> <p>13 is no epidemiologic data to support</p> <p>14 any of those biological pathways.</p> <p>15 QUESTIONS BY MR. SNIDOW:</p> <p>16 Q. Coherence. And this is about</p> <p>17 having the epidemiologic data not seriously</p> <p>18 conflict with other known facts about the</p> <p>19 history of the disease, right?</p> <p>20 A. That's what he says there, yes.</p> <p>21 Q. And he says for tobacco, it's</p> <p>22 the fact that cigarette smoking was coherent</p> <p>23 with the temporal rise that has taken place</p> <p>24 over the -- in the two variables over the</p> <p>25 last generation, right?</p>	<p style="text-align: right;">Page 545</p> <p>1 neurodevelopmental outcome.</p> <p>2 QUESTIONS BY MR. SNIDOW:</p> <p>3 Q. Experiment. This one can be</p> <p>4 done with animal studies, right?</p> <p>5 A. So there are experimental</p> <p>6 studies that attempt to characterize autism</p> <p>7 and ADHD in mice and rats. I don't believe</p> <p>8 that that's really a fair comparison because</p> <p>9 it's a bio -- it's a behaviorally based</p> <p>10 diagnosis.</p> <p>11 Q. And then analogy. And that's</p> <p>12 when you look at other drugs that have been</p> <p>13 accepted as causal and see whether the</p> <p>14 mechanism is similar?</p> <p>15 A. Correct.</p> <p>16 Q. And you don't think that</p> <p>17 valproic acid is a good analogy?</p> <p>18 MR. MURDICA: Object to the</p> <p>19 form.</p> <p>20 And I think you're out of time.</p> <p>21 When you took an early break after</p> <p>22 only 25 minutes, I thought it was</p> <p>23 because you were going to end early;</p> <p>24 otherwise, I wouldn't have agreed to</p> <p>25 it. But I think we're done now.</p>

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1 MR. SNIDOW: Okay. Can we do a
2 time check?
3 VIDEOGRAPHER: 6 hours,
4 56 minutes.
5 MR. MURDICA: Okay.
6 MR. SNIDOW: Four minutes?
7 MR. MURDICA: Yeah. It's still
8 amateur hour that you took an early
9 break and then didn't end early.
10 But go ahead.
11 MR. SNIDOW: You did the exact
12 same thing.
13 MR. MURDICA: I did not.
14 MR. SNIDOW: With Baccarelli.
15 You took a break, like, ten minutes
16 before you were done.
17 MR. MURDICA: Ten minutes
18 before I was done. You took a break
19 half an hour before you were done.
20 MR. SNIDOW: Oh. So that's how
21 the pros do it.
22 MR. MURDICA: It was amateurish
23 to take that break.
24 MR. SNIDOW: The pros do it --
25 the pros do it ten minutes before and

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1 not 30?
2 MR. MURDICA: That was
3 amateurish.
4 Go ahead.
5 MR. SNIDOW: Okay.
6 THE WITNESS: So I do not
7 believe that valproic acid is a
8 legitimate analogy for all the reasons
9 that I've described before, which
10 include the fact that we have precise
11 data on timing, dose and duration,
12 precise data on indication of use.
13 QUESTIONS BY MR. SNIDOW:
14 Q. Okay. And then he says here,
15 "None of my nine viewpoints can bring
16 indisputable evidence for or against the
17 cause-and-effect hypothesis."
18 Right?
19 A. He does say that.
20 Q. And you agree with that, right?
21 A. I do.
22 Q. And then he says, ultimately,
23 that it's a matter of judgment, right? That
24 there's no hard-and-fast rules for making the
25 causation determination?

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1 A. That's correct. And that's
2 what I believe, and that's what I've done in
3 my application of the Bradford Hill.
4 Q. And he says, "The ultimate
5 answer, though, is whether there's any other
6 answer equally or more likely than cause and
7 effect."
8 True?
9 A. That's correct.
10 Q. Okay.
11 A. And in my opinion, there is.
12 MR. SNIDOW: Okay. I'm going
13 to, I think, pass the witness, Jim,
14 but I've got some exhibits to mark.
15 And what number am I up to?
16 THE WITNESS: 631 is Baker,
17 which I think is the last one you gave
18 me. Or Bradford Hill, sorry.
19 MR. MURDICA: You're not
20 marking the things you agreed not to
21 mark, are you?
22 MR. SNIDOW: I am marking
23 these. And you can talk to the judge
24 or file a motion or whatever you want
25 to do.

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1 MR. MURDICA: Well, you agreed
2 not to mark them; otherwise, I said we
3 would have talked to the judge then.
4 And that's on the record.
5 So now that you're not marking
6 these, they're not going to be part of
7 the record, and the court reporter was
8 here, and she knows what was said, and
9 I'm going to ask the court reporter
10 not to mark them.
11 MR. SNIDOW: Okay. Do you want
12 to call the judge now to resolve this
13 dispute?
14 MR. MURDICA: It's your -- it's
15 your problem. You agreed not to do
16 it. It's not my problem. It's your
17 problem.
18 MR. SNIDOW: I'm not calling
19 the judge. I'm just marking my
20 exhibits.
21 MR. MURDICA: We are not going
22 to have exhibits that were created by
23 you. I made that very clear. And I
24 said if there was any dispute over it,
25 go to the judge then. I never would

<p style="text-align: right;">Page 550</p> <p>1 have allowed it to proceed if I knew 2 you were going to walk back your 3 agreement. 4 MR. SNIDOW: All right. Let's 5 call the judge then. 6 MR. MURDICA: Yeah, call the 7 judge. 8 MR. SNIDOW: No, I don't want 9 to call the judge. I want to mark my 10 exhibits. 11 MR. MURDICA: Well, it's your 12 problem. They're not -- you agreed 13 not to have them be exhibits. They're 14 not going on the transcript. 15 MR. SNIDOW: Yeah. And I have 16 some videos to mark, which I assume 17 you'll object to. 18 MR. MURDICA: I think you 19 should mark the entire thing, if 20 you're going to mark a video. 21 MR. SNIDOW: That, I'm actually 22 fine with, but it's going to take some 23 time. 24 MR. MURDICA: Okay. 25 MR. SNIDOW: Do you want me to</p>	<p style="text-align: right;">Page 552</p> <p>1 MR. MURDICA: You agreed not 2 to. It's not -- it's not happening. 3 That's totally unprofessional. 4 MR. SNIDOW: You can call the 5 judge. 6 MR. MURDICA: They won't be 7 part of the transcript because there 8 was already an agreement in front of 9 an officer of the court. 10 MR. SNIDOW: Yeah. You told me 11 there was some rule against it; we 12 looked into it, there's not, so... 13 MR. MURDICA: Look at what you 14 said on the transcript and what I 15 said. 16 MR. SNIDOW: You said that was 17 against the rules -- 18 MR. MURDICA: Okay. It doesn't 19 matter. You agreed to it. It's not 20 part of the record. 21 Okay. Let's continue. 22 MR. SNIDOW: Are you scared of 23 them? Are you frightened of them? 24 Why don't -- yeah. Why don't want 25 them be part of the record? They were</p>
<p style="text-align: right;">Page 551</p> <p>1 mark the whole thing? 2 MR. MURDICA: The videos? 3 MR. SNIDOW: Yeah. 4 MR. MURDICA: Yeah. 5 MR. SNIDOW: That, I can do. 6 MR. MURDICA: That would be the 7 reasonable thing to do. 8 MR. SNIDOW: Okay. 9 MR. MURDICA: Just like not 10 going back on an agreement. 11 MR. SNIDOW: And what I'm going 12 to do is, I'll mark the snips, and 13 then I'll mark the whole thing. So 14 you'll have -- you can call them .1, 15 .2, whatever. They're part of the 16 full exhibit, but you'll have them. 17 All right? 18 MR. MURDICA: Sure. 19 Okay. So are we going to 20 proceed now? You're not marking them, 21 so -- 22 MR. SNIDOW: I marked them. 23 MR. MURDICA: No, you didn't. 24 You didn't. 25 MR. SNIDOW: Look, see.</p>	<p style="text-align: right;">Page 553</p> <p>1 exhibits that we used with the 2 witness. 3 MR. MURDICA: They're things 4 that you created. They're things that 5 you created. They're not accurate, 6 and they're not appropriate exhibits. 7 And that's why you agreed to not call 8 the judge then when I told you you 9 could have called the judge. 10 I'm not going to argue with you 11 anymore. They're not exhibits. You 12 agreed for them to not be exhibits, 13 and you're not walking back an 14 agreement. That's -- I mean, that's 15 just pathetic. 16 All right. 17 MR. SNIDOW: You think that was 18 respectful? 19 MR. MURDICA: I don't think 20 it's respectful in the context of this 21 litigation for you to make an 22 agreement in the first hour of a 23 deposition and then walk it back at 24 the end of the deposition. 25 MR. SNIDOW: I really don't</p>

<p>Page 554</p> <p>1 think I made an exhibit {sic}. I</p> <p>2 said -- all I said is I'll take it</p> <p>3 off. That's all I said. I didn't say</p> <p>4 I'm never marking these. I didn't</p> <p>5 say, oh, yeah, you're totally right.</p> <p>6 I said, I'll take it off.</p> <p>7 MR. MURDICA: You can go read</p> <p>8 it and see if you -- see if that was a</p> <p>9 mootable of character.</p> <p>10 (Pinto-Martin Exhibits 632,</p> <p>11 633, 634, 635, 636, 637, 638, 639,</p> <p>12 639.1, 639.2, 639.3, 639.4, 639.5,</p> <p>13 639.6 and 639.7 marked for</p> <p>14 identification.)</p> <p>15 CROSS-EXAMINATION</p> <p>16 QUESTIONS BY MR. MURDICA:</p> <p>17 Q. All right. Are you ready to</p> <p>18 proceed, Doctor?</p> <p>19 A. Sure.</p> <p>20 Q. All right. So let's make a</p> <p>21 note of when we're starting.</p> <p>22 I'm just going to ask you a</p> <p>23 couple of questions about your examination</p> <p>24 today.</p> <p>25 A. Okay.</p>	<p>Page 556</p> <p>1 before, right.</p> <p>2 Q. And my question was going to</p> <p>3 be, have you ever seen that before?</p> <p>4 A. No. I didn't -- I didn't know</p> <p>5 what it was for or where it came from. I</p> <p>6 tried to make that clear.</p> <p>7 Q. Do you use that in your</p> <p>8 practice in any way?</p> <p>9 A. No. As I said, I've never seen</p> <p>10 it before, and I don't know how it's used.</p> <p>11 Q. Okay. And you were asked a</p> <p>12 bunch of questions on a particular sentence,</p> <p>13 I think it was from there, about whether a</p> <p>14 small sample size renders something</p> <p>15 inconclusive or actually negative.</p> <p>16 A. Uh-huh.</p> <p>17 Q. Do you remember those</p> <p>18 questions?</p> <p>19 A. I do.</p> <p>20 Q. And my question for you is</p> <p>21 this: Whether a study in the acetaminophen</p> <p>22 body of literature that you reviewed is</p> <p>23 inconclusive or negative, does it matter to</p> <p>24 your analysis -- your conclusion on causation</p> <p>25 here?</p>
<p>Page 555</p> <p>1 Q. Counsel for plaintiffs asked</p> <p>2 you about different confounding issues across</p> <p>3 the body of literature.</p> <p>4 Do you remember that?</p> <p>5 A. I do.</p> <p>6 Q. Okay. And did the individual</p> <p>7 studies each have elements of confounding</p> <p>8 that were or were not accounted for?</p> <p>9 A. Yes, and I tried to describe</p> <p>10 that. The set of confounders that the</p> <p>11 various cohort studies included vary, but</p> <p>12 they -- there are things that are included in</p> <p>13 some and not others, including, for example,</p> <p>14 maternal alcohol use and smoking, comorbid</p> <p>15 medical conditions, body mass index of the</p> <p>16 mother, stress during pregnancy, such things</p> <p>17 like that.</p> <p>18 But, again, they vary in terms</p> <p>19 of which ones controlled for which, so I</p> <p>20 didn't want to try to make a general</p> <p>21 statement about it.</p> <p>22 Q. You were asked questions about</p> <p>23 Exhibit 605, which is a Judicial Reference</p> <p>24 Manual?</p> <p>25 A. Right, which I had never seen</p>	<p>Page 557</p> <p>1 A. It does not have an impact on</p> <p>2 my conclusion on cause -- causation.</p> <p>3 Q. Why not?</p> <p>4 A. Because my conclusion on</p> <p>5 causation is based on the body of evidence</p> <p>6 and all of the factors that we've described</p> <p>7 to date that are relevant to the methodologic</p> <p>8 issues within the literature.</p> <p>9 Q. You were asked --</p> <p>10 A. I think it's here. Are you</p> <p>11 looking for it?</p> <p>12 Q. No. I'm looking for the next</p> <p>13 one, trying to save time here.</p> <p>14 You were asked a question about</p> <p>15 Exhibit 615, the Ricci study.</p> <p>16 Do you remember --</p> <p>17 A. I do.</p> <p>18 Q. -- seeing that earlier?</p> <p>19 A. I do, yeah.</p> <p>20 Q. And do you remember counsel</p> <p>21 asked you questions about negative</p> <p>22 meta-analyses? Remember that question?</p> <p>23 A. Uh-huh.</p> <p>24 Q. Okay. Was Ricci even able to</p> <p>25 do a meta-analysis on the autism data?</p>

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1 A. No, and stated as much because
 2 of the heterogeneity of the studies.
 3 Q. Okay. Do you recall being
 4 asked about Exhibit 609, which I'm putting in
 5 front of you, that is an Olsen and Liew
 6 study?
 7 A. I do.
 8 Q. And counsel went back to that a
 9 few times today if you recall.
 10 Do you remember that?
 11 A. Yes, I recall.
 12 Q. Okay. And what was the year of
 13 that?
 14 A. I believe it was 2016.
 15 Q. And --
 16 A. Yeah. 2017 it says here.
 17 Yeah.
 18 Q. And counsel showed you that for
 19 his proposition that the confounders had --
 20 that Liew allegedly thought the confounders
 21 had been accounted for.
 22 Do you remember that?
 23 A. That is what this opinion seems
 24 to indicate, yes.
 25 Q. Okay. Have you seen, since you

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1 wrote your report, e-mails containing
 2 Dr. Liew's views on confounders that he wrote
 3 only three months ago?
 4 A. I have.
 5 Q. And what did you see Dr. Liew
 6 say about confounders?
 7 A. That he was worried about
 8 genetic confounding. I don't know that he
 9 used the word "worry," concerned maybe, and
 10 that he noted that there had been a
 11 significant drop in the reported association
 12 once genetics were controlled for, and that
 13 he himself now had data, PRS data, that he
 14 was going to use to address the question of
 15 confounding by genetics.
 16 Q. Okay. And have you seen that
 17 data published by Dr. Liew yet?
 18 A. No, and as I've said, I would
 19 be anxious to see it.
 20 Q. Okay. And did the DN -- did
 21 the Danish National Birth Cohort that he
 22 published his studies from have genetic data?
 23 A. No, they did not control for
 24 genetic confounding.
 25 Q. Okay. You were shown

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1 Exhibit 610 as well, which is the Gou study.
 2 A. Uh-huh.
 3 Q. Do you recall counsel showing
 4 you that as well earlier today?
 5 A. I do.
 6 Q. All right. And you were -- you
 7 were asked some questions about it, but I
 8 want to point you to something that counsel
 9 didn't show you or ask you about --
 10 A. Okay.
 11 Q. -- which is the second sentence
 12 of the conclusion, on page 205.
 13 A. "Nevertheless, caution is
 14 advised when considering whether the
 15 association is causal because potentially
 16 unidentified or inadequately -- inadequately
 17 controlled confounding factors in the
 18 included studies may have unpredictable
 19 effects on the overall association."
 20 And I have said that
 21 repeatedly. Like a meta-analysis is only as
 22 good as the data on which it relies, and we
 23 know that those data have potential
 24 confounders and biases.
 25 Q. And that was right in

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1 Exhibit 610 that counsel asked you other
 2 questions about, right?
 3 A. That's correct.
 4 Q. Okay. You were asked a lot of
 5 questions about, you know, were the
 6 science -- you were asked a lot of questions
 7 about whether you disagreed with certain
 8 publication authors.
 9 Do you remember those
 10 questions?
 11 A. I do.
 12 Q. And you were asked about
 13 whether, you know, they were trying hard,
 14 doing a good job, was it reasonable for them
 15 to publish their results.
 16 Do you remember questions like
 17 that?
 18 A. I do.
 19 Q. Okay. For the conclusion that
 20 you made that the body of literature that you
 21 reviewed that was addressed here today does
 22 not support a causal relationship between
 23 in utero acetaminophen exposure and the
 24 outcomes of ADHD and/or autism, can
 25 reasonable epidemiologists disagree on that

<p style="text-align: right;">Page 562</p> <p>1 conclusion?</p> <p>2 A. I don't think a reasonable</p> <p>3 epidemiologist could disagree with my</p> <p>4 conclusion based on this body of evidence</p> <p>5 that there is no cred -- credible support for</p> <p>6 a causal association between prenatal</p> <p>7 acetaminophen use and ASD or APAP -- ASD or</p> <p>8 ADHD.</p> <p>9 And so the answer is no.</p> <p>10 Q. Dr. Pinto-Martin, you issued a</p> <p>11 report, maybe at this point it's almost two</p> <p>12 months ago, right?</p> <p>13 A. Yeah, end of June, I believe.</p> <p>14 Q. Okay.</p> <p>15 A. End of July.</p> <p>16 Q. Since then, there's been</p> <p>17 numerous expert depositions of plaintiffs'</p> <p>18 experts and the defendants' experts, and the</p> <p>19 ones that have happened to date, have you</p> <p>20 reviewed their transcripts?</p> <p>21 A. I have.</p> <p>22 Q. Okay. Is there anything you've</p> <p>23 seen since you've issued your report, either</p> <p>24 in those deposition transcripts or from</p> <p>25 counsel today, that has changed your views</p>	<p style="text-align: right;">Page 564</p> <p>1 in this purported association, and</p> <p>2 that he himself was going to look at</p> <p>3 it in data that he now had that had</p> <p>4 PRS scores.</p> <p>5 QUESTIONS BY MR. SNIDOW:</p> <p>6 Q. But did he say that genetic</p> <p>7 confounding was likely in those e-mails?</p> <p>8 MR. MURDICA: Objection.</p> <p>9 Objection to the form.</p> <p>10 THE WITNESS: I don't believe I</p> <p>11 said that, and I don't believe -- I</p> <p>12 don't remember the specifics of the</p> <p>13 e-mail. I just looked at it and --</p> <p>14 QUESTIONS BY MR. SNIDOW:</p> <p>15 Q. Well, you talked about it with</p> <p>16 Mr. Murdica just now, right? You talked</p> <p>17 about those e-mails?</p> <p>18 A. Not just now. I saw the</p> <p>19 e-mails back whenever they showed -- when the</p> <p>20 lawyers showed them to me. I read them. I</p> <p>21 don't -- I didn't retain that. I don't</p> <p>22 remember precisely what he said.</p> <p>23 What I can say is that his --</p> <p>24 the message that he was putting forth is a</p> <p>25 very different message from the opinion piece</p>
<p style="text-align: right;">Page 563</p> <p>1 and your conclusions in your report in any</p> <p>2 way?</p> <p>3 A. Absolutely not.</p> <p>4 MR. MURDICA: Okay. I don't</p> <p>5 have anything further.</p> <p>6 MR. SNIDOW: Okay.</p> <p>7 REDIRECT EXAMINATION</p> <p>8 QUESTIONS BY MR. SNIDOW:</p> <p>9 Q. Very briefly.</p> <p>10 You mentioned some e-mails</p> <p>11 with Dr. Liew.</p> <p>12 When did you look at those?</p> <p>13 A. In the last two weeks, I would</p> <p>14 say.</p> <p>15 Q. And it's your testimony that he</p> <p>16 said that genetic confounding was likely?</p> <p>17 MR. MURDICA: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: I don't recall</p> <p>20 the specifics of the e-mail, but the</p> <p>21 gist of the message was that he had</p> <p>22 seen results where genetic confounding</p> <p>23 was illustrated, I'm imagining it was</p> <p>24 the Gustavson study, and was concerned</p> <p>25 about that as a potential confounder</p>	<p style="text-align: right;">Page 565</p> <p>1 that you showed me, the Olsen and Liew piece.</p> <p>2 And in addition, he's written</p> <p>3 another opinion piece, another commentary,</p> <p>4 that is also -- talks about the noncausal</p> <p>5 back door that can be opened if there's a</p> <p>6 genetic factor that both increases the use of</p> <p>7 APAP and increases the risk of ASD or ADHD.</p> <p>8 So I just point it out because</p> <p>9 I think a thoughtful epidemiologist should</p> <p>10 consider that, and he is, and I hope he</p> <p>11 publishes on it.</p> <p>12 Q. You said "and he is"?</p> <p>13 MR. MURDICA: Objection.</p> <p>14 THE WITNESS: Well, he says</p> <p>15 he's going to --</p> <p>16 QUESTIONS BY MR. SNIDOW:</p> <p>17 Q. No, he is a thoughtful</p> <p>18 epidemiologist?</p> <p>19 A. If he -- if he proceeds with</p> <p>20 what he said he was going to do, which is to</p> <p>21 use new evidence to address prior</p> <p>22 associations that he's reported to see if</p> <p>23 there's confounding, I think that is a --</p> <p>24 that shows integrity.</p> <p>25 MR. SNIDOW: Okay. I have no</p>

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1 further questions.
 2 MR. MURDICA: All right. Thank
 3 you.
 4 VIDEOGRAPHER: The time is
 5 5:48 p.m., and we are off the record.
 6 (Deposition concluded at 5:48 p.m.)
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1 CERTIFICATE
 2 I, CARRIE A. CAMPBELL, Registered
 3 Diplomate Reporter, Certified Realtime
 4 Reporter and Certified Shorthand Reporter, do
 5 hereby certify that prior to the commencement
 6 of the examination, Jennifer Pinto-Martin,
 7 Ph.D., MPH, was duly sworn by me to testify
 8 to the truth, the whole truth and nothing but
 9 the truth.
 10 I DO FURTHER CERTIFY that the
 11 foregoing is a verbatim transcript of the
 12 testimony as taken stenographically by and
 13 before me at the time, place and on the date
 14 hereinbefore set forth, to the best of my
 15 ability.
 16 I DO FURTHER CERTIFY that I am
 17 neither a relative nor employee nor attorney
 18 nor counsel of any of the parties to this
 19 action, and that I am neither a relative nor
 20 employee of such attorney or counsel, and
 21 that I am not financially interested in the
 22 action.
 23
 24 CARRIE A. CAMPBELL,
 25 NCRA Registered Diplomate Reporter
 Certified Realtime Reporter
 California Certified Shorthand
 Reporter #13921
 Missouri Certified Court Reporter #859
 Illinois Certified Shorthand Reporter
 #084-004229
 Texas Certified Shorthand Reporter #9328
 Kansas Certified Court Reporter #1715
 New Jersey Certified Court Reporter
 #30X100242600
 Louisiana Certified Court Reporter
 #2021012
 Notary Public
 Dated: September 11, 2023

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1 INSTRUCTIONS TO WITNESS
 2 DATE: September 11, 2023
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it. You are signing
 10 same subject to the changes you have noted on
 11 the errata sheet, which will be attached to
 12 your deposition.
 13 It is imperative that you return
 14 the original errata sheet to the deposing
 15 attorney within thirty (30) days of receipt
 16 of the deposition transcript by you. If you
 17 fail to do so, the deposition transcript may
 18 be deemed to be accurate and may be used in
 19 court.
 20
 21
 22
 23
 24
 25

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1 ACKNOWLEDGMENT OF DEPONENT
 2
 3
 4 I, _____, do
 5 hereby certify that I have read the foregoing
 6 pages and that the same is a correct
 7 transcription of the answers given by me to
 8 the questions therein propounded, except for
 9 the corrections or changes in form or
 10 substance, if any, noted in the attached
 11 Errata Sheet.
 12
 13 Jennifer Pinto-Martin, Ph.D., MPH DATE _____
 14
 15 Subscribed and sworn to before me this
 16 _____ day of _____, 20 _____.
 17 My commission expires: _____
 18
 19 Notary Public
 20
 21
 22
 23
 24
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